Animal Welfare Information Center

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CONGRESS IN SESSION

by Cynthia Smith

- **H.R. 3393 A bill to amend the Animal Welfare Act to prevent the crime of pet theft.**

Introduced on May 7, 1996, by Jon Fox (R-Penn.) and referred to the Committee on Agriculture. Referred to the Subcommittee on Livestock, Dairy, and Poultry on May 13, 1996. Executive comment requested from the U.S. Department of Agriculture on May 20, 1996. This act may be cited as the "Family Pet Protection Act of 1996."

"Section 7 of the Animal Welfare Act is amended to read as follows: (a) It shall be unlawful for any research facility to purchase, lease, or acquire in a calendar year a live or dead dog or cat, in or affecting commerce, for research or educational purposes, except from-- (1) a licensed dealer who bred and raised the dog or cat; (2) a pound that is in compliance with sections 6, 28, and 30, and that acquired the dog or cat from the legal owner of

(cont'd p.16)

ALSO IN THIS ISSUE...

The IACUC Process: Facilitating Science in a Well-Managed Animal Care and Use Program

by

G. David Ledney, Ph.D., Radiation Medicine Department and Institutional Animal Care and Use Committee; LTC Clayton L. Hadick, USA, M.P.H., D.V.M., ACLAM , Veterinary Sciences Department; and Robert H. Weichbrod, Ph.D., M.B.A., RILAM , Veterinary Sciences Department, Armed Forces Radiobiology Research Institute, Bethesda, Maryland

Introduction

Communication among people with diverse backgrounds and vested interests is difficult at best. This is especially true among those concerned with animal welfare issues.

An Institutional Animal Care and Use Committee (IACUC) is by its nature a focal point (fig. 1) for communication among all parties who have a stake in the use of animals in biomedical research. While each group may seek resolutions that favor its own interests, the guidepost for IACUC members, when evaluating animal use proposals, must be the ethical use of animals in research and testing.

During a typical review process, IACUC members are accustomed to hearing, "You can't do that," "You don't know the science," "You have no authority," "I've done this so many times already," "That will take too long," "You are an impediment to research." (8) When a frustrated investigator says, "Just tell me what I need to do," an IACUC member may be

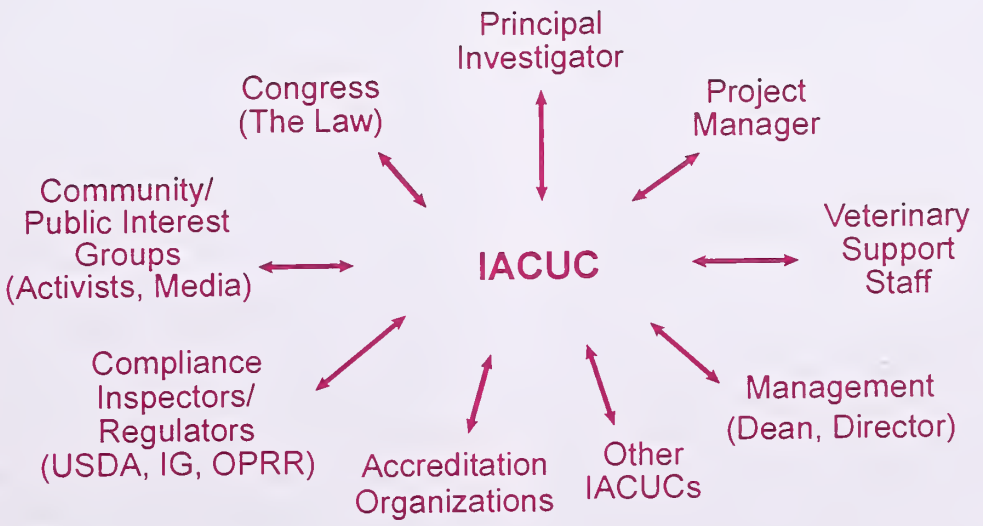

Figure 1. IACUC communication pathways.

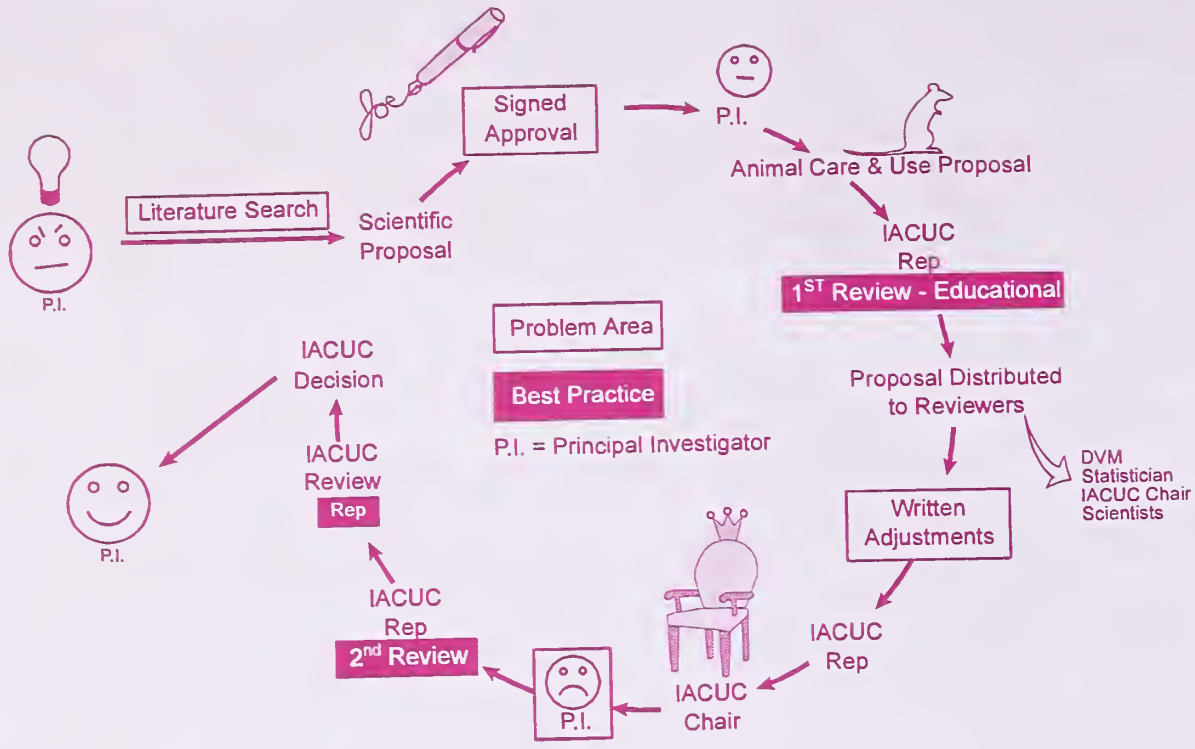

Figure 2. Pathway for successful scientific and animal care and use proposal review at the Armed Forces Radiobiology Research Institute.

tempted to respond, "You want me to do your animal use protocol for you?" Of course, that is not the intent of the process. The goal of this communication is to describe a review process by which all participants may expedite approval of an animal care and use proposal.

Process Structure

It is incumbent upon each IACUC to minimize frustration by establishing a simple, practical animal care and use form and evaluation process. The participation of all staff members in initial development of the form will instill a sense of ownership of and responsibility (1) for the review process. At the same time, however, the animal care and use proposal form must be open to review and refinement as needed to handle new requirements or findings.

The IACUC form and the review process will vary according to local organizational needs and constraints. Ideally, the IACUC forms should be available on the computer (**best practice**) as well as in hard-copy editions. Computer editions must be tamperproof to prevent errors of omission or commission.

The idea of a standardized animal care and use proposal form has been adopted by the Department of Defense (DoD) and may be considered by others nationwide. Standardization would enhance collaboration between organizations that share animal resources. Likewise, an institution that follows a national standard would be less open to criticism by the United States Department of Agriculture and animal rights groups.

An IACUC, according to the DoD general counsel (6), is a decision-making body, not an advisory committee. Hence, appropriate attention should be given to member selection. At the Armed Forces Radiobiology Research Institute (AFRRI), service on the IACUC is voluntary. Members and alternates who represent the scientific departments are appointed by the chief laboratory officer, as are a statistician and clinical veterinarians. Two high school biology teachers represent the community (9). All IACUC members serve at the discretion of the laboratory director, and the scientific department representatives usually serve for 2 or 3 years. There are no paid administrative and secretarial staffs.

A significant strength (**best practice**) of the Institute's American Association for the Accreditation of Laboratory Animal Care (AAALAC)-accredited animal care and use program is the participation of IACUC members, executive, administrative, scientific and veterinary departmental staff, and community representatives in seminars offered by the Public Responsibility in Medicine and Research (PRIM&R), Applied Research Ethics National Association (ARENA), American Association of Laboratory Animal Science (AALAS), and Scientist's Center for Animal Welfare (SCAW). Many scientific and veterinary staff members have trained at the Animal Welfare Information Center (AWIC), in Beltsville, Maryland, to increase their computer-based bibliographic search skills. Participation at these meetings is open to all staff members and does not replace in-house training mandated by the Animal Welfare Act.

Scientific Proposal Review Process

The IACUC proposal review process commences when an investigator conceptualizes a research idea for which internal or extramural research funds will be requested (fig. 2). Generally, a rigorous and relevant literature search (**problem area**) is conducted in order to generate a grant or scientific proposal to acquire research funds. If literature searches are limited to the National Library of Medicine CD-ROM's (Medline, Toxline, etc.) and the investigator's own holdings, the IACUC cannot be assured that the proposed use of animals is not unduly redundant. Therefore, it is recommended that the investigator work with a local librarian or the AWIC staff to determine which computer-based bibliographic services should be used. Because the numerous electronic databases can be expensive to use, it is incumbent on the investigator to work with a librarian to develop a strategic approach to the bibliographic search.

At AFRRI, the scientific review process is administratively separated

(cont'd p. 14)

Reducing Animal Numbers: Sequential Sampling

by
Arnold S. Chamove, B.A., M.A., Ph.D., M.Phil., F.I.Biol., Department of Psychology, Palmerston North, New Zealand (A.S.Chamove@Massey.ac.NZ)

How much is it worth to be able to cut the number of animals needed in an experiment in half? Is it worth your reading on?

One way of reducing the number of animals needed in an experiment is to use more sophisticated statistics, not a more difficult method, in fact less difficult once you know how. I'll describe a technique enabling you to shave the number of animals used by about 30-40 percent or more and to do your statistical analyses faster and easier.

"What is the cost of all this generosity?" I hear you ask. To have all these advantages you must have some estimate of three things: your control/baseline mean, control/baseline variance, and the effect size. You will most likely have all of these already, but you will need to use them in a slightly different way than you have in the past.

Intuition

There are three ways to decide on the number of subjects to use in an experiment, and I will describe them in descending order of their efficiency (and their ethical nature). The first is to use one's intuition, an estimate, an educated guess if you wish. It is well known by now that these subjective estimates of the number of subjects needed are usually overestimates.

Try a test on yourself to see if you have been or would be incorrect in your estimates of the numbers of subjects needed: Most people are aware that the intelligence quotient (IQ) is devised so that it has a mean of 100 and a standard deviation of 15. That means that if you take a random sample of people, the mean of their IQs will be close to 100. To give some feeling for the IQ, the mean of students at university is higher, about 120; genius is 130. Having a standard deviation of 15 means that 68 percent of people fall within 15 points of the mean plus or minus; in other words 68 percent of people have an IQ of between 85 and 115. Ninety five percent of people have an IQ that falls within two standard deviations (30 points) of the mean. That is one of the valuable characteristics of the standard deviation, having 95 percent of the sample within two standard deviations of the mean.

With that in mind, if I said I had found something that would raise someone's IQ 30 points (or 20 points, or even 10 points), how many subjects do you feel you would have to test in order to come to a statistical decision at the 0.05 level for each of these three problems? To make it more realistic, a drug company has offered to pay you a lot of money for this substance that you claim will raise IQ, but you will have to pay them a lot before they start. Therefore you don't want to say it increases IQ if it doesn't as that will cost you a lot, nor say it doesn't if it does as you will miss out on a lot of money. Let's say the substance also causes side effects. So, you don't want to overestimate the number of subjects needed to be sure of detecting a difference, or underestimate to be cautious. If you have underestimated, you might miss something important. If you have overestimated, you might be exposing some of your subjects to unnecessary suffering. How many subjects do you think you would have to give the drug to see if the substance works? Give your estimate:

(a) for an increase of 10 points =__,
(b) for an increase of 20 points =__,
(c) for an increase of 30 points =__.

The true values are given in the last line of this paragraph. I predict you will have overestimated especially in the condition when the effect was the most extreme, the 30-IQ-point condition. The answer for 10 points is 20 subjects, for 20 IQ points is 5, and 30 IQ points need only two subjects to detect the difference.

When most of us are planning an experiment, there is more involved than just guessing. Normally, we decide on the number of subjects based on (a) how many subjects there are available, (b) the cost to us, or to them, of the test procedure, (c) and finally that feeling about how many we will need to make the sort of decision that we hope to make. If there are few subjects available, testing is costly or distressing to subjects, or we feel the effect we want to show is a big one, then we use fewer subjects. If there are lots of potential subjects, testing is quick or perhaps even beneficial to the subjects, or the effect that we are trying to detect is a tiny one, we select more subjects.

A common question that is posed by students or experimentally naive colleagues is, "How many subjects do I need?" The answer still most commonly given is, "As many as I can afford to test."

Power Analysis

The second way to decide on the number of subjects needed is to do a power analysis. This technique is more efficient when compared with the estimate described above in that fewer subjects are required in order to arrive at a decision with the same degree of certainty. I did a power analysis to arrive at the figures used to answer the three questions above, those about how many subjects would be needed to see if the compound raised IQ.

A few of the existing statistical packages will compute the number of subjects needed with varying degrees of ease. Here, I have used STATISTICA by StatSoft (5) and I found it easy to use. Power analysis is hidden away in the Process Analysis section of STATISTICA. You may find it of interest to know that power analysis (and sequential sampling, described below) is commonly used by "quality control engineers...to determine how many items from a batch to inspect in order to ensure that the items in that batch are of acceptable quality." (5, p. 3,571).

To use the technique, you need to know three things: First, you need to know the comparison mean, the mean of the control group. In our example above the mean was an IQ of 100, but it could be the average number dying under some treatment, the percentage normally infected, the amount of pain under some procedure, the average frequency or duration of aggression without the recommended intervention, etc.

Second, you need some measure of variability, generally the standard

deviation. We used the value of 15 in our IQ example as it is widely known. If you have a mean for your comparison condition, you will usually already have a measure of variability.

Your third requirement is an estimate of effect size. We are not ordinarily asked for an estimate of effect size, but we often have one in mind. To use the IQ example again, if our substance only increased IQ by one point, and even if the effect were statistically significant, we would say that the substance was not valuable, that the effect size was so small as to be uninteresting, that no one would buy it. We know that an extremely small effect size is worthless.

There are a number of things that can help in determining effect size. The most common is other research. I carry out research in the area of environmental enrichment, formerly with monkeys and more recently with farm animals (1). One difficulty in that area is deciding on an appropriate effect size, and I know of no research where anyone has reported estimating effect size.

Change is easy; improvement is easy too. Almost anything you do to a monkey alone in a zoo enclosure, to a rat living in a bare laboratory cage, or to a pig farmed in a small crate will produce a change in their behavior. But is that change large enough to be important, large enough to be worth the expense to make that change? Is the improvement to the welfare/behavior of chickens large enough to warrant the cost of increasing the cage size?

Other help in determining whether an effect size is sufficiently large to be important is *percent of variance accounted for.* This is measured by r^2 in correlation and by omega-squared (2^2) in analysis of variance.

Recently, I have been assessing the effects of visual shelter on levels of stress and aggression in farm animals. Now, if planting a row of trees will reduce aggression in deer, as it will (8), will you the farmer plant the trees? Before speculating on an answer, you might be excused for asking (a) the cost of the trees and (b) the degree to which the aggression will be reduced--that is, the cost/benefit analysis. The benefit question is the same question the researcher must ask him/herself to get an estimate of effect size. How big a reduction in aggression must I find before I conclude there are benefits in providing visual shelter?

The literature suggests that in monkeys, in bulls, and in rats, providing a visual barrier behind which some of the animals can hide will reduce aggression by about 50 percent. We might set our effect size near that value. Using that value, we can then calculate the number of subjects we need to test to see if visual shelter reduces aggression by at least half in deer. (In case you're interested, it does.)

The program STATISTICA asks for the mean under the null hypothesis (IQ = 100), the standard deviation (IQ = 15), the effect size (IQ = 130 in our example above). It also asks for the alpha level (conventionally p = 0.05), the beta level (conventionally = 0.1), and whether the predictions are one- or two-tailed. After you enter these numbers, STATISTICA presents you with the number of subjects you will need to test--sounds easy.

Then you carry out your experiment, do your test for statistical significance (for example, t-test or ANOVA), and draw your conclusions. But there is an even easier method and one that is even more powerful.

Sequential Sampling

The third and best way to decide on the number of subjects that you will use in an experiment is called sequential sampling or the sequential experiment. While in the above examples the subject size was either estimated or calculated and then fixed before the experiment was carried out, *in the sequential experiment the number of subjects to be used is undecided and is determined only by the sample observations as they are completed.* That is the only difference between sequential sampling and the power analysis described above. You test one subject, look at his data, decide, test another subject, look at her data, decide, and so on.

In the fixed sampling experiments we all are familiar with, there are two possible decisions we can make: Either reject the null hypothesis and then conclude the groups are different, or fail to reject the null hypothesis and by default accept an alternative hypothesis, usually concluding the groups are not different. In the sequential experiment there are three possible decisions. The first two are the same as above, but the third is a different one: Either keep sampling, or stop sampling and conclude that a decision about the null and alternative hypotheses cannot be made. In other words, more samples are needed before a decision can be made as to whether the two groups differ or not.

This third alternative, let's call it the devil's alternative, is likely only when the variability is large and the difference between the means is very small. This condition is the only penalty of using sequential sampling, other than having to have an estimate of effect size.

To actually employ sequential sampling, you need only have the same equipment as for the power analysis--mean, variability, and effect size. You can enter these values into STATISTICA and, instead of pressing the *fixed sample* button, you press the *sequential sampling* button.

To illustrate, we will use some real data and superimpose that data on the graph generated by Statistica, just as one would do in reality. The only difference is that I have already tested all the subjects, whereas in a sequential sampling experiment, one would only test one or two subjects at a time. We will return to a monkey enrichment experiment I did, illustrated in a widely displayed video (6). To test to see if a small forage box would improve conditions for individually housed marmoset monkeys, I decided that the monkeys would have to be more active, in fact at least double the levels of activity when monkeys live in a bare cage without the ability to forage. The control or baseline levels for a group of monkeys living singly in bare cages was 12.9 percent of the day spent active (with a standard deviation of 9.7). Our effect size of doubling means that with the forage box, they must spend at least 26 percent of the day active for us to conclude that the effect of the forage box is important.

To restate the techniques that I could have used to decide how many subjects to use, I could just guess how many to use. How many monkeys would you say I would need to use in order to see if the forage box increases total daily activity? Answers please, now ____. I would have estimated a minimum of 15 but only 13 were available to test at baseline; this further decreased to 9 by the time of the retest.

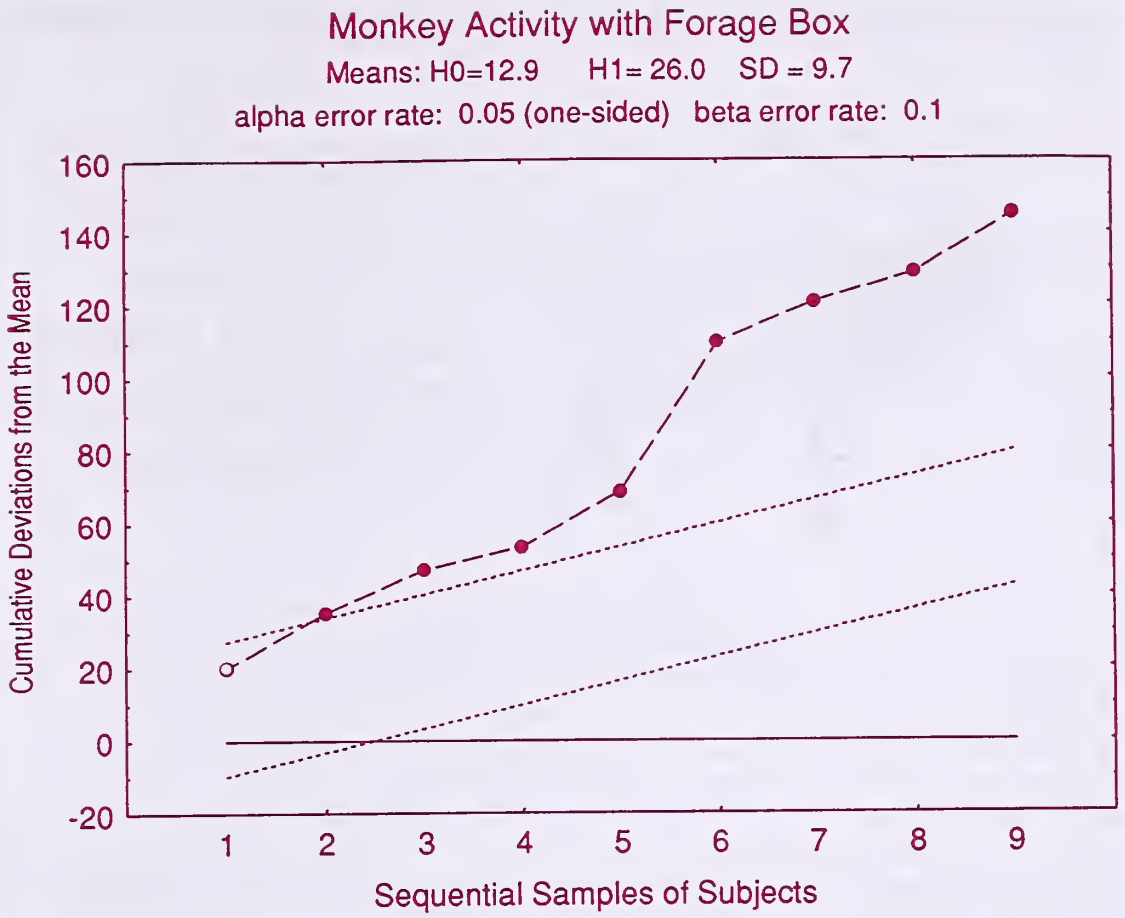

Figure 1. Cumulative deviations from the control mean in activity by nine individually housed Cotton-top tamarins.

I could have done a power analysis, so I have done one now. In the power analysis, STATISTICA helps us calculate that we would need nine monkeys. Or I could have used sequential sampling, and I have done this in detail below.

The following is the procedure for sequential sampling. To see if the manipulation is significant at the prescribed effect size, you simply graph your data. To do this you give STATISTICA the information we have already ascertained, namely mean, standard deviation, and effect size, and it will produce the figure reproduced here (fig. 1). Superimposed on the graph is the data I actually obtained. STATISTICA will plot that data too if you have it. The sequential sampling plan produces a graph on which there is one parallel corridor (a two-tailed test has two corridors) leading gradually away from the baseline of "no difference." You plot the mean obtained from each subject in turn, actually the deviation score for that subject from baseline. If that plot remains within the corridor, it means that you can neither conclude that your forage box is effective nor that it is useless, that is, you should keep sampling. If the plot drops below the corridor you can conclude that behavior with the forage box is no different from the control condition; if the plot goes above the corridor, you conclude the forage box is effective in improving behavior, that is reject the null hypothesis.

In the example we have used, I could have tested just one subject and plotted her data on the graph. You can see if that subject's improvement score had been over 30, that is if the subject had increased her score from the baseline mean of 13 to at least 43, her score would have fallen above and outside the corridor and I would have been able to stop testing and then conclude that the forage box had at least doubled activity and the effect was significant at $p = 0.05$. In fact her score was only 33, having improved 20 points above baseline, and that score of 20 is plotted on the graph. The second monkey had a score of 28, 15 above baseline, and so 15 is plotted. The cumulative scores of the two monkeys now extends above the corridor, just above the corridor, and testing can be stopped.

To arrive at a decision with the same degree of certainty as I did with just 2 subjects using sequential sampling, I would need to have tested 9 subjects had I done a power analysis, and I would have used 15 had I gone by my own intuition based on over 30 years of research with monkeys. You can see that a power analysis will reduce the number of subjects used by almost half, but the sequential sampling technique reduces the number needed even further. In this example, sequential sampling reduced the number of subjects by 70 percent from the power analysis and even more from my educated guess.

Why such a huge reduction? If the forage box had improved behavior only by the bare minimum allowed, 13, it still would have taken only 4 subjects before going outside the corridor. But because the box was so effective, almost trebling the amount of activity, the scores rapidly exceeded that corridor of "no significant difference." That is one of the unexpected benefits of sequential sampling not found in any form of fixed sampling. In the case that the effect size is even greater than postulated, even fewer subjects are needed.

Imagine that in the study described above, the experimental manipulation was a painful one. We would want to know if it worked but would also wish to keep the subjects used to a minimum in case it was not effective. Or we might want to minimize subject use because we wanted to know if the compound was toxic. In this example, I should use only two subjects and could if I use sequential sampling. To reiterate, in almost all cases, sequential sampling procedures are preferable to fixed sampling procedures because sequential sampling is more powerful in that fewer subjects are required in order to arrive at a decision with the same degree of certainty.

Ethical Considerations

Is it unethical not to use sequential sampling if it is appropriate to use it? I would argue that it is unethical. If you are carrying out a procedure in which you wish to use the fewest animals possible to come to a conclusion with a desired level of confidence, you should use sequential sampling unless there are good reasons not to do so. To paraphrase, this is a technique to reduce to an absolute minimum the amount of distress imposed on animals.

Why don't ethics committees insist on it? Probably because they have never heard of it. Until recently, the computations to calculate power and

sequential sampling have been tedious, and the technique has not been described in textbooks. STATISTICA has changed all that.

Do you want to read more about sequential sampling? The math-phobic can read about these techniques in a chapter by Edwards (2), the behavioral scientist in a friendly text by Leavitt (3), the stats-sophisticate can consult Pyzdek (4) or go back to the man himself, to Wald (7), and finally the statistics package STATISTICA (5) will take the practitioner quickly and painlessly through the mechanics of actually computing the numbers. I was unable to find procedures for sequential sampling in other commonly used statistical packages.

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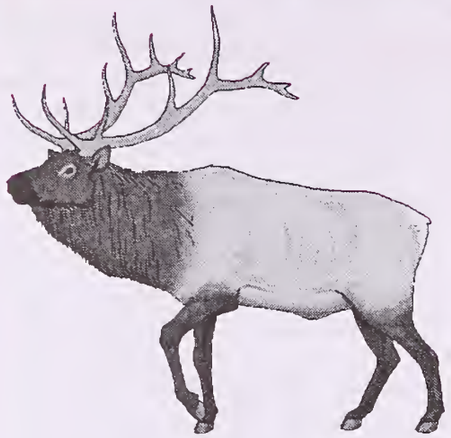

USDA PROPOSES TO REGULATE CAPTIVE CERVIDS UNDER TB ERADICATION PROGRAM

WASHINGTON, April 4, 1996--The U.S. Department of Agriculture is proposing to include captive cervids (such as deer, elk, and moose) under its regulations for the bovine tuberculosis eradication program. This action would set standards for tuberculosis testing and identification of captive cervids for interstate movement and international export certification similar to requirements currently in place for cattle and bison.

"National disease control standards for tuberculosis in captive-raised deer and elk are critical for the eradication of this infectious disease from the United States," said Donald W. Luchsinger, deputy administrator for veterinary services with the Animal and Plant Health Inspection Service, a part of USDA's marketing and regulatory programs mission area. Such standards will not only protect the health of the growing cervid industries, but will also reduce the risk of spreading disease to the cattle and bison industries, to wildlife, and to humans."

Various animal health experts, including the National Academy of Sciences, have determined that captive cervids are a potential source of tuberculosis infection. In the past 10 years, outbreaks of bovine tuberculosis in livestock in New York, Montana, and Pennsylvania and in Canada in New Brunswick and British Columbia were caused by tuberculosis-infected captive cervid herds.

To address this emerging animal health issue, APHIS veterinarians have worked with state animal health officials and the cervid industry associations over the past few years to develop the "Uniform Methods and Rules (UMR) for Tuberculosis Eradication in Cervidae." These are minimum program standards and procedures for movement, testing, and identification similar to the UMR for cattle and bison. The UMR for cervids became effective on May 15, 1994.

Notice of this action was published in the April 4 Federal Register, pp. 14982-14999.

Public comments received by APHIS may be reviewed at USDA, Room 1141 South Building, 14th and Independence Avenue, S.W., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to review comments are requested to call ahead on (202) 690-2817 to assure entry into the comment reading room.

NOTE: USDA news releases and media advisories are available on the Internet. Access the USDA Homepage on the World Wide Web at http://www.usda.gov ■

Effects of the Shift to Alternatives on Industrial Practices

by
DeWayne H. Walker, D.V.M., M.S.
Manager, Laboratory Animal Research Services, 3M Corporation, St. Paul, Minnesota

Introduction

The intent of this article is to provide an overview of industrial proactivity in embracing the 3R's of alternatives--refinement, reduction, and replacement. Because of the diversity of industrial product lines, one can appreciate that one shoe does not fit all in terms of regulations, politics, marketing, and public opinion. It would be inappropriate to describe industry as a single entity in addressing alternative activity, but it does lend itself to analysis along the four classical industrial groups: cosmetics, household and industrial chemicals, pharmaceuticals, and medical devices.

In reality, public opinion has already broken industry up into categories if one acknowledges public sentiment regarding animal testing. Two 1990 polls, a Gallup Poll printed in *Advertising Age* and an unpublished Roper Poll conducted on behalf of industry, denoted similar data referencing society's impression of the use of animals in product testing (9, 6). These polls found that only one-third of those surveyed condoned the use of animals in the testing of cosmetics and household products. About one-half of those polled accepted animal usage in research for over-the-counter drugs, whereas the use of animals in testing of prescription drugs and medical devices was accepted by about two-thirds to three-quarters of those surveyed. One may venture the generalized statement that whereas drugs and medical devices appear to be viewed by the general public as necessities, cosmetics and household products appear to be viewed by the same public as niceties.

The Cosmetic Industry

The cosmetics industry is a $45-billion-a-year business with thousands of products embodied in 33 Food and Drug Administration (FDA) classifications (13,18). Cosmetics are defined by the Food, Drug and Cosmetic Act as "articles intended to be applied to the human body for cleaning, beautifying, promoting attractiveness or altering the appearance without affecting the body's structural function" (8). The key words in this definition are "intended" and "body's structural function." Intended use of the cosmetic must be clearly labeled and if the safety of a cosmetic product is not adequately substantiated for that intended use, the product is considered misbranded and may be subject to regulatory action. The physiological, or functional, altering of the body differentiates drugs from cosmetics. The FDA regulates this difference by not requiring premarket approval of cosmetics. At the same time, however, the FDA does expect that the manufacturer of a cosmetic has conducted toxicological and other appropriate tests to substantiate the safety of the product and can provide this data if challenged by the agency. While it has become fashionable for some manufacturers to apply the "cruelty-free" label to their products (indicating that animals were not used during safety testing), this claim can be misleading (see sidebar--The Cruelty-free Label).

In vitro tests and other nonanimal methods for safety evaluation have come a long way and are being used in industry as initial screening procedures. However, given a new cosmetic derivative or a cosmetic incorporating a drug component, a standardized in vivo test, such as the Draize Ocular Irritation Test, may be in order. This in vivo test is still considered valuable in predicting human eye irritants when the irritation is subtle or when the chronic recovery phase data may be equally as important as the initial acute exposure data. Industry, in cooperation with regulatory agencies, has established multiple refinements to obtain the required data while minimizing the potential for pain or distress. Evaluation of the agent's pH and the use of the primary dermal irritation tests are routinely used to screen out agents likely to evoke a response beyond moderate irritation (17). Agents having passed the preliminary screening could conceivably go on to the classic test but with the following refinements in place: use of three animals vs. the standard of six; use of smaller volumes of solution installed in the eye; use of one animal to evaluate an unknown and await a response before continuing or discontinuing with the remaining test animals; and use,

The Cruelty-Free Label

The animal activist organization People for the Ethical Treatment of Animals (PETA) in its "Caring Consumer Campaign" lists over 600 companies marketing cosmetic products in the absence of animal testing (4). This claim raises the question as to how a product's safety can be substantiated without the use of animals. There are several possible explanations: 1) Major brand companies have been in the cosmetic business for decades and have massive files of well established safety data (for most commonly used ingredients) obtained from years of animal testing and human clinical trials. By combining this information with data obtained from established in vitro methods, these companies have been able to derive a high level of confidence in their safety data to bring new products to market. 2) Some have stretched the definition of "cruelty-free" or "without cruelty" by not conducting animal testing on the final formula though they have conducted animal testing on ingredients and/or have suppliers provide animal test data. 3) A more deceptive option is to have the animal testing conducted overseas. 4) A hypocritical option is to establish an arbitrary cut-off date for previously conducted animal testing. The classic example of this technique is using animal-tested ingredients after a 5-year moratorium (7, 8). Finally, either from arrogance or naiveté, the manufacturer may elect to take advantage of the market ploy by just using the "cruelty-free" label without justification because as yet there are no legal penalties for doing so.

D.H. Walker

when applicable, of anesthetics in the eye (10). In part, because of refinements to the Draize Ocular Irritation Test and use of available in vitro methods, the number of rabbits used in the cosmetic industry between 1980 and 1989 was reduced by 87 percent (12).

Chemical and Household Products Industry

The household and industrial chemical group is extremely diverse, touching all our lives every day in the home, the workplace, and the outdoors. The Environmental Protection Agency (EPA) has listed over 100,000 chemicals in our environment, with several thousand new chemicals being added each year (11). The definition of this group is "those products that are of a non-medical nature that are created to enhance personal, household, industrial and agricultural applications." This group is also under attack by animal activists and, in fact, People for the Ethical Treatment of Animals (PETA) has a Top 50 product boycott list that includes many companies supplying these products (4). However, the chemical and household products group, unlike the cosmetic group, is frequently called on by government agencies to provide safety data obtained from in vivo testing. A risk assessment of a given chemical may be required by: the U.S. Department of Transportation (DOT) to classify chemicals for handling and transportation; the Occupational Safety and Health Administration seeking to protect workers via the manufacturer identifying "gross, mostly local toxic effects"; and the Environmental Protection Agency to assess the potential environmental impact of a products release into the environment. Needless to say, the general population expects the manufacturer to provide toxicological data should there be accidental or deliberate exposure. The poison control centers in the United States receive on average 1.6 million calls a year; 900,000 of these calls relate to accidental poisoning of children and about 40,000 to animal poisoning. (14) The bottom line is an obvious need to safeguard the general public from accidental injury and to achieve this data through effective product testing.

In the area of alternatives for this industrial group, we find the introduction of the Corrositex Test. This test, introduced in 1993, marked the first acceptance by a Federal agency (DOT) of an in vitro test as an alternative to animal testing for regulatory purposes (21). The corrosive classification of a given chemical can be determined by this test based on the time it takes the chemical to cause damage to a collagen matrix top layer, which approximates a full-thickness layer of skin cells, and elicit a color indicator response in a second layer. Although there are categories of chemicals for which this test is not applicable, the test has been shown to be 97.7 percent accurate in identifying all commercially available corrosive chemicals on the Department of Transportation Hazardous Material Table (5).

Pharmaceutical Industry

A drug is defined as "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and other animals; and articles (other than food) intended to affect the structure or any function of the body of humans or other animals." (8) The pharmaceutical industry is an area of great potential for development of alternatives to animal testing. Whereas cosmetic/consumer products impart there benefit with little or no effect on physiological functions, drugs purposely affect the biological processes controlling life. As a consequence, drug interaction necessitates considerable investigation to ensure both efficacy and safety. Drug introduction to market is an extremely expensive and time-consuming endeavor. While a cosmetic may take but 6 months to reach the consumer, and a typical consumer/industrial chemical 2 to 3 years and $1 to $2 million to get to market, that is but a blink of an eye and pocket change to the drug industry (18). In the process of drug development and approval, an average of 6.5 years is spent in the screening and preclinical testing of as many as 5,000 candidate compounds. Only 5 of 5,000 compounds that enter preclinical testing make it to human testing, which consumes another 6 years. FDA review and approval entails on average another 2.5 years, and typically only 1 of the 5 drugs will be approved. The bottom line is an average of 15 years from laboratory to medicine chest at an investment cost of $359 million. The Pharmaceutical Research and Manufacturers of America estimates that this will reach $1 billion in cost per drug early in the next century (2).

Although the cost and time associated with clinical testing and FDA review may be inescapable now and in the future, the use of in vitro methods in the discovery and preclinical phase has been instrumental in streamlining these stages. Computer modeling and structure-activity relationships have been invaluable in the early screening of candidate drugs. Agar overlay for cytotoxicity, Ames mutagenicity assay, cell transformation assay, and yeast mutagenicity assay are among those tests in common use for early toxicity screening. In the preclinical phase, a meaningful reduction in animal numbers has been attributed to the use of tiered testing, approximate lethal dose, and the Up and Down Method to replace the classic LD50 (3).

Medical Device Industry

Finally, there is the medical device industry. Medical devices are defined as, "any health care product that does not achieve any of its principal intended purposes by chemical action in or on the body or by being metabolized" (8). This group consistently fares well in animal use surveys, likely because of the perception by the general public that the products they generate have immediate and measurable impact on the quality of life and the saving of lives.

To accomplish their intended purpose, medical devices require varying degrees of invasiveness, which in turn necessitates various levels of safety and efficacy testing. Medical devices are evaluated by a scheme consisting of a battery of in vitro and in vivo tests (19). For those devices that are in contact with the intact skin only, the normal scheme requires the:

1) intracutaneous irritation test in the rabbit
2) maximization test for hypersensitivity in the guinea pig
3) cytotoxicity via agar overlay
4) acute systemic test in mice

For those medical devices passed into the body, such as catheters, the testing includes tests 1-4 above plus:

5) in vitro hemolysis in whole blood
6) rabbit pyrogen or in vitro Limulus amebocyte lysate (LAL) for pyrogenic effect
7) rabbit muscle implants for biocompatibility
8) Ames mutagenicity to evaluate mutagenic potential

For those devices implanted for a period in excess of 30 days, such as heart valves, tests 1-8 are required as well as:
9) chronic toxicity
10) carcinogenesis testing

In reviewing the tests making up the evaluation scheme, a major area for development of alternatives is that of biocompatibility testing. The interaction of implanted biomaterials on the body tissues is an area that has received much attention as a result of the controversy surrounding breast implants. The present in vivo methods involve a considerable investment of time and resources with enough scientific uncertainty in the results to suggest the need for the investigation of in vitro methods to either replace or supplement these tests. In the meantime, the medical device industry has done a good job of embracing alternative methods for training. Such implements as surgery computer simulation, foam cadavers, mannequins, use of cadaver tissues for laser training, and the laparoscopic "black box" have been useful adjuncts in common use in this industrial group. In the research and development phase, such refinements as telemetry implants, vascular access ports, and electronic access ports have been well-received alternatives to more invasive data collection methods.

Industrial Survey

To augment this general overview of how alternatives affect industrial practices, a small (n = 14) informal survey was conducted among companies representing the cosmetic/chemical and drug/medical device industries. The intent of the survey was to ascertain the general attitude of the industries towards the consideration, or experience in use, of alternative methods. In general, all industries indicated an appreciation for the coming of age of alternative methods; however, as one might predict, there was a difference of opinion between the two groups. Questions were presented with a range response of "strongly agree" to "strongly disagree" with additional comments encouraged. Those questions invoking the most interesting responses are noted below:

1."Your firm's move to consideration of alternatives is/was influenced by the animal activism movement"? The response was not too unexpected as cosmetic/chemical companies indicated an agreement to strong agreement with this statement. Drug and medical device companies were neutral to indicating disagreement with the statement. This result aligned well with the public opinion of increased acceptance of animal usage for the drug and medical device industry.

2."Your firm's move to consideration of alternatives is/was influenced by **direct** monetary considerations"? The response for the cosmetic/chemical group was somewhat surprising. One would expect that some test cost savings would be achieved by these groups given their significant experience with non-animal alternatives. However, the majority responded as disagreeing with the statement. The plausible explanation is that even if cost savings are presently being realized, the use of alternative tests has yet to recover the costs of development and validation of these methods. Drug and medical device companies were neutral on this question, likely indicating inadequate experience to pass judgment.

3. "Your firm's move to consideration of alternatives is/was influenced by **indirect** monetary considerations"? Both cosmetic/chemical and drug/medical device companies were neutral when answering this question on using alternatives as a marketing tool. Given the use of "cruelty-free" advertising by some beauty product firms, this result may seem inconsistent on the part of the cosmetic firms. However, the cosmetic companies surveyed were major reputable companies claiming a strong aversion to seeking a market advantage through such advertising.

Each group was surveyed as to their main change in business practices since the advent of alternatives. The cosmetic/chemical group emphasized public opinion aspects, notably: animal work is reviewed at a much higher administration level, increased use of human subjects, and establishment of much stronger public relations departments. The drug and medical device group laid most emphasis on scientific enhancements noting increased management involvement in test selection, an enhanced level of innovative thinking about the feasibility of alternatives, and a noticeable improvement in acceptance and use of validated nonanimal methods.

When questioned on what nonanimal tests were being used by their firms, the groups reported that: all are currently using structure-activity relationships, deductions based on similar products, cell cultures, and comprehensive literature searches for toxicity of raw materials. The cosmetic and chemical industries use commercially available artificial tissues and drugs/medical device industries use well-established in vitro methods such as agar overlay for cytotoxicity, Ames mutagenicity assay, and cell transformation assay. Given the opportunity to add to this survey list, the cosmetic/chemical group noted that they are using the bovine corneal opacity test, chorioallantoic membrane test, and yeast phototoxicity assay. Drug and medical device groups are using combinatorial chemistry, gene sequencing, and tissue slices.

The Worldwide Picture

The industrial market is a worldwide market, so legislation affecting one region can have significant repercussions on the far side of the globe. Such may be the case with impending enforcement of legislation in Europe. In 1986, Directive 86/609/EEC was passed into law establishing a European commitment to the 3R's--reduction in number of animals used, refined techniques to minimize pain, and replacement of live animals with nonanimal techniques. In particular, article 7.2 states, "An experiment shall not be performed, if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonable and practicably available." In 1991 the Commission of the European Communities consummated the push for alternative procedures by the establishment of the European Centre for the Validation of Alternative Methods (ECVAM) (20). This melting pot of European scientists was tasked with coordinating the validation of alternative test methods, functioning as a focal point for information exchange, establishing and managing an alternative data base, and promoting an international dialogue for encouraging the development, validation, and regulatory acceptance of alternative test methods (1). This sequence of events took on potential worldwide market impact when on June 14, 1993, the Council of Ministers approved a 6th Amendment to the Cosmetic Directive 76/768/EEC. The preamble of this document includes the following background statement with reference to cosmetics:

"whereas testing on animals of ingredients or combinations of ingredients should be banned as from 1 January, 1998."

The directive came with the loophole that should the ECVAM scientists not demonstrate scientifically equivalent nonanimal test methods, the deadline could be extended minimally another 2 years (15). However, ECVAM progress to date would indicate the probability of some methods meeting this criteria by the January 1, 1998 date (16).

The potential impact of the EEC Directives is of future concern mostly from the perspective of interpretation. The question may be asked, "Will U.S. regulators accept European alternative methods and validation procedures? Will there be an agreement on the vagueness of ingredients vs. final formulation?; that is, if a U.S. company initially develops a product with intent for it to be a drug, thereby likely requiring some animal testing, what if later it is not efficacious as a drug but would suit as a cosmetic. Does the initial animal testing of the chemical disqualify it for later reclassification? Will the varying U.S. and European definition of cosmetics result in major consequences for multi-nationals (that is, trade barriers)? For example, in the United States, such products as sunscreens, antiperspirants, antibacterial soaps, and fluoride tooth paste are considered drugs, whereas in Europe they are considered cosmetics. A company is, thus, in the potential bind of satisfying U.S. regulators by performing safety animal testing only to be disqualified in the European market with the same product because it has undergone animal testing.

Conclusions

It is perhaps fair to say that at this point in time the cosmetic and, to a lesser degree, the chemical industries have embraced alternative methods that primarily support the R's of reduction and replacement. The drug and medical device industries have likewise demonstrated success in the R of reduction and meaningful advancements in refinements. The R of replacement is likely a long-term consideration for the drug and device industries given the complexity of their respective chemical/material entities and their purposeful direct interaction with the body. It is generally encouraging to see the extent of alternative usage or at least consideration of alternatives across all of the industrial groups surveyed. It is apparent that, for the future, the financial impact of market barriers resulting from laws requiring alternatives may be a far greater direct influence on development and use of alternatives than public opinion and the animal activism movement. As in vitro tests are developed and validated, and harmony is established between regulatory bodies and international groups, the full spectrum of the 3R's will be hopefully realized.

For more information, Dr. Walker may be contacted at phone: (612) 736-3747, fax: (612) 736-1519, e-mail: dhwalker@mmm.com or by writing to 3M Corporation, Bldg. 270-2A-08, 3M Center, St. Paul, MN 55144-1000.

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Frequently Asked Questions About Safe Pair-Housing of Macaques

by
Viktor Reinhardt, D.V.M., Ph.D., Animal Welfare Institute, Washington, D.C.

Permanent pair-housing of previously single-caged macaques has become an accepted way of providing the animals with a more species-appropriate environment in the research laboratory setting. The push towards this change has come primarily from animal care personnel and veterinarians, but there is also an increasing number of scientists who recognize that macaques need social companionship for their behavioral health.

Using a simple pairing technique (1), I have transferred several hundred adult rhesus and stumptailed macaques from single-housing to isosexual pair-housing arrangements at the Wisconsin Regional Primate Research Center. There are several frequently raised questions regarding details of the pair-formation and subsequent pair-housing protocol that I want to address here for the benefit of those who want to make sure that institutionalizing pair-housing of macaques at their facility will not jeopardize the safety of the animals.

1. Why is it necessary that potential partners establish a rank relationship prior to pairing?

The dominance-subordination relationship is a basic condition for the two macaques living together. The animals do not have to engage in possibly injurious fighting but really establish such a relationship during a non-contact familiarization period in a double cage with a grated partition allowing visual, olfactory, and auditory communication. When later being introduced to each other in another cage without a partition, the subordinate partner will respect the dominance of the other, and the two therefore have no reason to fight.

2. How do I know that two animals have established a rank relationship?

Grinning, withdrawing, or turning away when being looked at or when being approached by the neighbor and threatening-against-the-observer-and--glancing-back-at-the-neighbor are indicators of subordination. A relationship is settled if any or all of these behaviors are strictly shown by only one of the two partners; this animal is the subordinate, the other is the dominant one of the dyad. Aggressive behaviors such as threatening or slamming against the cage dividing panel are not suitable to reliably determine the rank relationship between two partners.

3. How long does it take two monkeys to establish a rank relationship?

About 75 percent of the animals show clear signs of a dominance-subordination relationship within the first day of noncontact familiarization (2).

4. Can I pair the animals on the first day of familiarization?

Yes, after you have seen that one partner is subordinate to the other. It is advisable, however, to pair such animals the next morning in order to have a whole day to ascertain their compatibility.

5. Is it really necessary to pair the animals in a different double cage, rather than simply removing the grated partition?

The partners of some, but not all, pairs will engage in vicious territorial antagonism at the moment you remove the cage dividing grated panel, regardless of the fact that they already have a well-established rank relationship. It is impossible to predict which pairs will react in this way since cage neighbors across the aisle may instigate such disputes. With the safety of the animals a priority, it is therefore recommended not to take chances but make it a rule to transfer all potential pairs into a different area where everything is strange to them except the other companion. The management of the pair-housing program can be simplified if a familiarization cage is set aside in a designated test room and potential pairs moved from there to new home cages.

6. What is the cumulative time that I have to invest to form a compatible pair?

About 30 minutes.

7. Is there a way that I can avoid subjecting paired animals to the stress associated with temporary separation during research procedures?

Many procedures--such as venipuncture, topical application of drugs, intramuscular injection, remote sampling via a tether--can be done in pair-housed animals without separating the partners. If two companions have to be physically separated -- for example, during postsurgical recovery, restraint chair experiments, metabolic experiments, food intake studies, urine/fecal collection studies --there is no reason for not allowing them to keep continual visual and auditory contact with each other with the help of a transparent cage divider or a mobile cage. Husbandry-related routine separations --for example, during TB testing, weighing, physical/pregnancy examination--are unlikely to distress the animals because they quickly learn that they are reunited after a short while.

8. Are male pairs less compatible than female pairs?

No, as long as you keep them in male-only areas to avoid sexual competition triggered by the sight of a receptive female.

9. If a pair becomes incompatible, can I pair the animals with other partners?

Yes, the sooner the better.

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Comparing Cage Space Requirements for Nonhuman Primates in the United States and in Europe

by
Viktor Reinhardt, D.V.M., Ph.D., Cathy Liss, and Christine Stevens,
Animal Welfare Institute, Washington, D.C.

Fifty-six investigators working closely with laboratory nonhuman primates were asked what they thought could be done to the home environment to improve their animals' well-being (1). The most frequent of 28 suggested recommendations was for larger cages (6). A comparison of cage space requirements in the United States (5, 10) with those in Europe (3) supports this recommendation. Table 1 lists the respective stipulations for animals up to 25 kilograms (kg) (Animals over 25 kg are considered only in the U.S. rules.).

Minimum floor area for singly-caged primates is on average 44 percent smaller in the United States than in Europe. The difference is statistically significant ($p < 0.01$) and ranges from -20 percent to -64 percent.

If a compatible cage mate is introduced, the floor area does not have to be enlarged in Europe. In the United States, however, it must be increased according to the companion's body weight. Supposing that paired partners have the same body weight, minimum floor area would have to be doubled in the United States but not in Europe. Under such a circumstance, pair-housed animals would be allocated 7 percent more floor space in the United States than in Europe. This difference is insignificant ($p < 0.01$).

Minimum height requirements for single- or pair-housed primates are on average 22 percent lower in the United States than in Europe. The difference is significant ($p < 0.01$) and ranges from +1 percent to -39 percent.

European rules recommend that perches be installed so that the animal (s) can utilize not only the horizontal but also the vertical space of the cage. U. S. rules recommend perches among other examples of environmental enrichment for providing means of expressing species-typical activities.

Discussion

While floor area requirements for pair-housed nonhuman primates are similar in the United States and in Europe, floor area requirements for single-housed animals are markedly less in the United States than in Europe. Single-caging is the prevailing arrangement for primates in U.S. laboratories (6, 7). This implies that most animals are being kept in cages that are too small.

Minimal height requirements in Europe take the biological adaptation of nonhuman primates to a three-dimensional, arboreal environment (2, 4, 8, 9) into account by providing adequate space for the installation of a perch. The individual not only can normally sit and walk *on* the perch but also *under* the perch (fig. 1). Minimum U.S. height requirements do not meet this criterion in most instances. The perch has to be placed either too high, thereby not leaving enough leeway for normal balancing and posturing on it, or the perch has to be placed too low, thereby blocking part of the minimum floor area (fig. 2). Either situation is unacceptable.

Weight of primate (kg)	Floor Area (m^2)			Height (cm)		
	Europe	U.S.A.	(Difference) percent	Europe	U.S.A.	(Difference) percent
< 1	0.25	0.15	(-40)	60	51	(-15)
1-2	0.35	0.28	(-20)	75	76	(+1)
2-3	0.35	0.28	(-20)	75	76	(+1)
3-4	0.50	0.40	(-20)	80	76	(-5)
4-5	0.50	0.40	(-20)	80	76	(-5)
5-6	0.70	0.40	(-43)	85	76	(-11)
6-7	0.70	0.40	(-43)	85	76	(-11)
7-8	0.90	0.40	(-56)	90	76	(-16)
8-9	0.90	0.40	(-56)	90	76	(-16)
9-10	1.10	0.40	(-64)	125	76	(-39)
10-11	1.10	0.56	(-49)	125	81	(-35)
11-12	1.10	0.56	(-49)	125	81	(-35)
12-13	1.10	0.56	(-49)	125	81	(-35)
13-14	1.10	0.56	(-49)	125	81	(-35)
14-15	1.10	0.56	(-49)	125	81	(-35)
15-16	1.50	0.74	(-51)	125	91	(-27)
16-17	1.50	0.74	(-51)	125	91	(-27)
17-18	1.50	0.74	(-51)	125	91	(-27)
18-19	1.50	0.74	(-51)	125	91	(-27)
19-20	1.50	0.74	(-51)	125	91	(-27)
20-21	1.50	0.74	(-51)	125	91	(-27)
21-22	1.50	0.74	(-51)	125	91	(-27)
22-23	1.50	0.74	(-51)	125	91	(-27)
23-24	1.50	0.74	(-51)	125	91	(-27)
24-25	1.50	0.74	(-51)	125	91	(-27)

Table 1. Minimum cage space requirements for nonhuman primates in the United States (USDA 1991) and in Europe (EECC 1986).

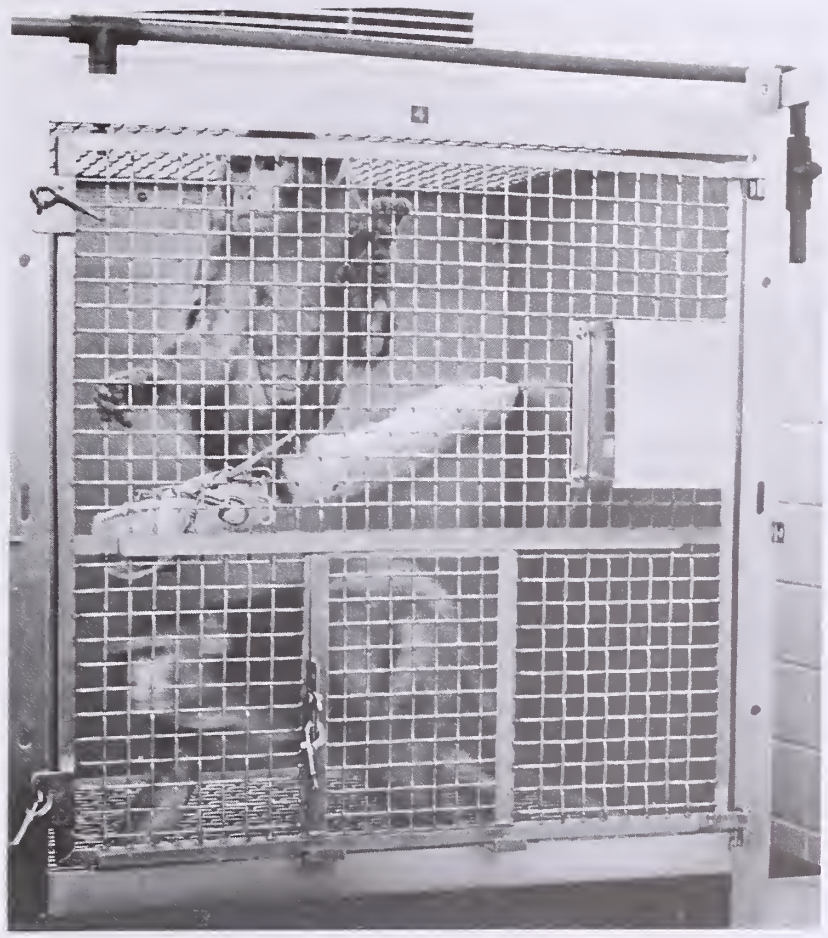

Figure 1. This 85-cm-high cage meets the European minimum requirements for primates of the body weight class 6-7 kg. It allows the installation of a perch, or other climbing surface, in such a way that an animal can normally sit and walk not only on but also under it. The U.S. minimum requirements of 76-cm height do not fulfill this condition.

Conclusion

Minimum space requirements for caged non-human primates are subminimal in the United States when compared to Europe. The European space allocations are not perfect, but they may serve as an example of earnest intention to address the animals' spatial needs for species-typical locomotor behaviors, postures, and postural adjustments within the given constraints of cage confinement.

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Figure 2. This 77-cm-high cage meets the U.S. but not the European minimum requirements for primates of the body weight class 5-6 kg. The height of the cage does not permit installation of a perch without blocking part of the minimum floor area for normal sitting and walking. In the United States, a 77-cm-high cage is legal for animals weighing up to 10 kg! In Europe, only animals weighing up to 3 kg could legally be housed in such a cage.

IACUC cont'd from p.2

from the IACUC review process. Thus, two documents—the scientific proposal and the animal use proposal—must be prepared. Unfortunately, an investigator may try to make parts of the scientific proposal also function as the animal care and use proposal by embedding scientific rationale and literature citations into the nontechnical explanation of the purpose in the animal use proposal and in the nontechnical description of the experimental design (**problem area**). This approach routinely causes IACUC community members to defer the proposal until only nontechnical language and selected references are used to describe the work. Furthermore, it provokes in-depth discussion that should be reserved for a specific scientific review.

At our institute, the scientific proposal must be approved by a hierarchy of scientific administrators. This arrangement, in addition to providing a review of the science, serves as a check on the duplication of effort relative to animal use (**best practice**). This process, however, takes time because the approval authorities are also involved in other administrative activities (**problem area**). Therefore, it is incumbent on all reviewers (especially those at the lowest supervisory level) to detect animal welfare issues that should be corrected before the animal use proposal is submitted for IACUC review.

IACUC Review Process

Once the scientific proposal is approved, the animal care and use proposal must be prepared. Before writing the animal care and use proposal, the investigator can benefit from informally reviewing the IACUC form with the departmental representative and the clinical veterinarian. Problem areas should be identified early to avoid extensive adjustments to the animal use proposal later.

When the investigator completes the IACUC form, it is submitted to the departmental representative for initial review. Since the representative may be familiar with the proposed research, input on fundamental scientific issues can be provided to the investigator in a diplomatic manner (2, 5). The review is provided as hard-copy, and the investigator adjusts the animal use proposal.

The investigator must realize that the animal use proposal is submitted into a process and is not evaluated against a static checklist of requirements. Each IACUC representative should also acquire the skill to teach an investigator about the animal welfare requirements as set forth in the IACUC form or ensure that the investigator knows where to find pertinent information.

The departmental representative submits the animal care and use proposal to the IACUC chairperson once he/she is satisfied with the investigator's adjustments in response to his/her comments. The IACUC chairperson, who evaluates all animal care and use proposals, distributes copies to a subcommittee composed of a clinical veterinarian, a statistician, two IACUC committee members acquainted with the subject species (5), and other IACUC members (7), if any, who wish to evaluate the proposal. So, including the departmental representative, the animal use proposal is reviewed by at least six different IACUC members.

Professionalism and respect for all parties during the animal care and use proposal review is maintained in the following way. Each IACUC subcommittee member evaluates the proposal and submits to the IACUC chairperson a written unsigned critique like that for a peer-reviewed manuscript. Further, the IACUC chairperson inspects all critiques to ensure the fair and impartial application of animal welfare requirements. All unsigned critiques are then turned over to the investigator's IACUC representative who in turn releases all of them at one time to the investigator (**best practice**). If the investigator has serious concerns relative to fairness and impartiality of the critiques, he can appeal to the IACUC chairperson for adjudication and relief.

The failure to provide all critiques to the investigator at one time (**problem area**) can cause significant frustration. Although the IACUC reviewer may intend to save time for the investigator by providing an individual critique, the investigator could end up revising the proposal six times instead of once.

The review process described above is reasonably straightforward. Even so, proposals reviewed by the IACUC are often returned for additional information. When this happens, an investigator may view the IACUC and the IACUC chairperson as authoritarian (**problem area**), a critical situation that requires the utmost diplomacy and expert guidance on how to respond to the concerns documented in the critiques. It is important to explain to the investigator that specific scientific merit is not questioned and that the IACUC's concerns are with animal welfare and proper documentation (3) that satisfies all concerned parties indicated in figure 1. Common reason for rejection of the animal care and use proposal is the lack of strong and thorough assurance documentation relative to duplication of research and alternatives for painful procedures. Investigators, in an effort to save time, may use the literature search used to establish the research proposal rationale (**problem area**). The IACUC must insist on a literature search that establishes whether pain can be alleviated or reduced and, if applicable, why less painful procedures cannot be used. As stated previously, valuable assistance in the performance of literature searches can be provided by the local librarian or the staff at AWIC.

The astute investigator responds to all the critiques and indicates in some manner to his/her IACUC departmental representative that all concerns of all IACUC reviewers were addressed. The departmental representative reviews the revised document (**best practice**) for compliance with adjustment requests and, if it is satisfactory, indicates to the IACUC chairperson that the animal care and use proposal is ready for full committee review. The animal care and use proposal is then placed on the IACUC agenda, which is distributed several days prior to the meeting.

The fully adjusted animal care and use proposal must meet with the approval of the departmental representative. At the meeting of the full IACUC membership, the chairperson again offers to all IACUC members the opportunity to review the adjusted animal use proposal. If there are no requests, the departmental representative (**best practice**) provides an oral review of the proposal and stands for questions from the whole commit-

tee. The investigator may be invited and may request to present the review. If not presenting the review, the investigator is alerted to be in the vicinity of the meeting area to answer technically difficult questions. Based on the relationship that develops during the review process, most investigators trust their departmental representative to present the review. Likewise, many investigators are uncomfortable or even intimidated by a committee of their peers who reviewed their work.

When all concerns have been addressed by the investigator, the animal care and use proposal is brought to a vote. If present, the investigator and anyone with a vested interest is invited to leave the room. Voting by secret ballot or by voice is offered. An "approved" decision is justified if all parties have been attentive to the IACUC role of oversight of the animal welfare rules and regulations. If the proposal is approved, the decision is documented in the meeting minutes, the proposal is stamped, signed, and dated by the IACUC chairperson, the investigator is notified, and the original document is kept in the permanent IACUC files. If disapproved, the proposal is returned to the investigator via the IACUC representative for additional information or revision.

Conclusion

The Animal Welfare Act mandates that the IACUC is the formal overseer of animal welfare in the local research environment. However, this does not release any participant from ensuring that animals are humanely used and that integrity (1) is central to all research and testing endeavors. Education relative to animal welfare, inside and outside of the IACUC, is a continuing process (fig. 3). Enlightened staff realize that there are many avenues to this knowledge and that, once achieved, produces better research products.

(The figures were presented in part at the 46th Annual American Association for Laboratory Animal Science Oct 15-19, 1995, Baltimore, MD.)

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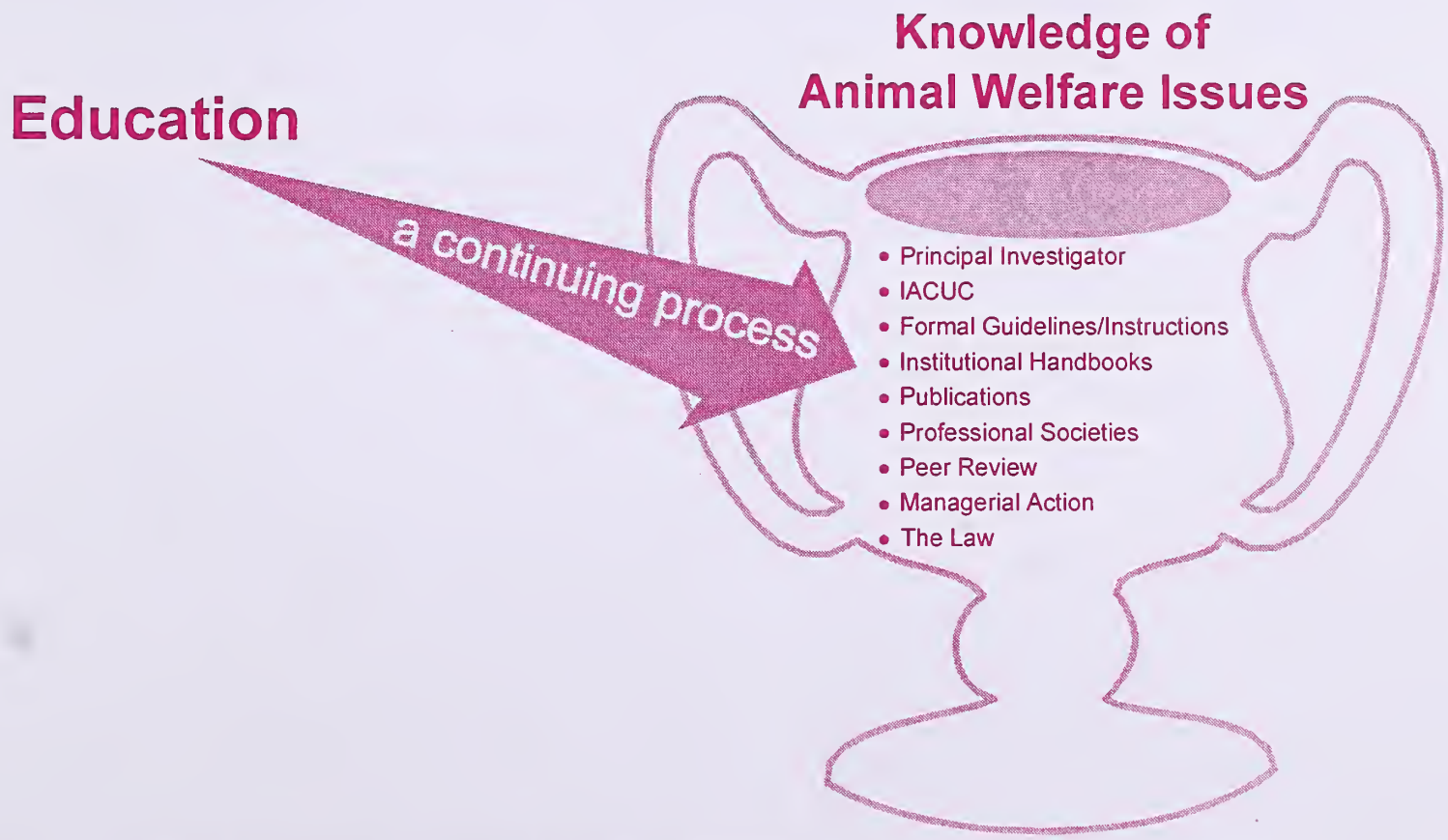

Figure 3. Sources of continuing education leading to knowledge in animal welfare issues.

Legislation cont'd from p.1

the dog or cat; (3) a person who bred and raised the dog or cat and donated during the calendar year not more than one animal to a research facility or Federal research facility; (4) a research facility that is registered with the Department of Agriculture; or (5) a Federal, State, or local government agency which is not a pound."

Section 7 increases the length of time required for pounds to hold dogs or cats from 5 days to 10 days.

- **H.R. 3398 To amend the Animal Welfare Act to ensure that all dogs and cats used by research facilities are obtained legally.**

Introduced May 7, 1996, by Charles Canady (R-Fla.) and referred to the Committee on Agriculture. Referred to the Subcommittee on Livestock, Dairy, and Poultry on May 13,1996. Executive comment requested from the U.S. Department of Agriculture on May 20, 1996. This act may be cited as the "Pet Safety and Protection Act of 1996."

"Section 7 of the Animal Welfare Act is amended to read as follows: (a) Use of Certain Dogs and Cats--No research facility or Federal research facility may use a dog or cat for research or educational purposes if the dog or cat was obtained from a person other than a person described in subsection (c). (b) Selling, Donating, or Offering Dogs and Cats--No person, other than a person described in subsection (c), may sell, donate, or offer a dog or cat to any research facility or Federal research facility. (c) Permissible Sources--Persons from whom a research facility or a Federal research facility may obtain a dog or cat for research or educational purposes under subsection (a) and persons may sell, donate, or offer a dog or cat to a research facility or a Federal research facility under subsection (b) are--(1) a dealer licensed under section 3 [of the Animal Welfare Act] who has bred and raised such a dog or cat; (2) a publicly owned and operated pound or shelter that--(A) is registered with the Department of Agriculture; (B) is in compliance with section 28(a)(1) and with requirements for dealers in section 28 (b) and (c); and (C) obtained such dog or cat from its legal owner, other than a pound or shelter; (3) a person who is donating such dog or cat and who--(A) bred and raised such dog or cat; or (B) owned such dog or cat for not less than 1 year immediately preceding the donation; (4) a research facility licensed by the Department of Agriculture; and (5) a Federal research facility licensed by the Department of Agriculture. "

The act does not require a pound or shelter to release dogs or cats to research facilities.

- **H.R. 2934 A bill to eliminate certain Federal programs and subsidies.**

Introduced on February 1, 1996, by Peter Blute (R-Mass.) and referred to the Committee on Ways and Means; and in addition to the Committee on Agriculture. Referred to the Subcommittee on Livestock, Dairy, and Poultry; the Subcommittee on Resource Conservation, Research, and Forestry; and others on February 13,1996. This act may be cited as the "Taxpayers Savings Act of 1996."

Section 4 states that "the last proviso of the matter under the heading 'Animal and Plant Health Inspection Service' of Title I of the Rural Development, Agriculture, and Related Agencies Appropriations Act, 1986 (P.L. 100-202) is amended by striking ': *Provided further,* That hereafter,' and all that follows through 'Animal Damage Control activities.'"

- **S. 1701 A bill to end the use of steel jaw leghold traps on animals in the United States, and for other purposes.**

Introduced on April 24,1996, by Claiborne Pell (D-R. I.) and referred to the Senate Environment and Public Works Committee.

"It is the policy of the United States to end the needless maiming and suffering inflicted on animals through the use of steel jaw leghold traps by prohibiting the shipment in interstate commerce or foreign commerce of the traps and articles of fur from animals that were trapped in the traps."

"SEC. 3. PROHIBITED ACTS AND PENALTIES.

(a) ACTS INVOLVING ARTICLES OF FUR--An article of fur may not be imported, exported, shipped, or received in interstate commerce or foreign commerce if any part of the article is derived from an animal the trapping of which in a steel jaw leghold trap permitted the production of the article. (b) ACTS BY PERSONS--It is unlawful for a person knowingly--

(1) to import, export, ship, or receive an article of fur in violation of subsection (a);

(2) to deliver, carry, transport, or ship by any means, in interstate commerce or foreign commerce, a steel jaw leghold trap; (3) to sell, receive, acquire, or purchase a steel jaw leghold trap that was delivered, carried, transported, or shipped in violation of paragraph (2) or; (4) to violate a regulation issued by the Secretary [of the Interior] under this section."

Related bill H.R. 1404.

- **H. R. 3173 To establish, wherever possible, nonanimal acute toxicity testing as an acceptable standard for Government regulations requiring an evaluation of the safety of products by the Federal Government.**

Introduced on March 17,1996, by Tom Lantos (D-Calif.) and referred to the Committee on Commerce and the Subcommittee on Health and Environment. This act may be cited as the "Consumer Products Safe Testing Act."

"The Congress finds that the Federal Government has discouraged the use of nonanimal acute toxicity tests through regulations that mandate or encourage the use of animal acute toxicity tests, or by not prescribing other, less costly, more accurate and humane alternatives,... and; many manufacturers are reluctant to use nonanimal tests without encouragement from the Federal Government."

Sec. 3. (a) states that "not later than one year after the date of enactment of this Act, each Federal department or agency head shall--(1) review and evaluate any regulation, guideline, or recommendation issued by that department or agency which requires, recommends, or encourages the use of the Draize or other animal acute toxicity test for the purpose of evaluation of the safety of a regulated product; (2) review and evaluate nonanimal alternatives with the potential for partial or full replacement of the Draize or other

animal acute toxicity test for some or all of the products regulated; and (3) promulgate regulations, guidelines, or recommendations that specify a nonanimal acute toxicity test or battery of tests should be used instead of an animal acute toxicity test unless that Federal department or agency head determines that the nonanimal acute toxicity test or battery of such tests is less likely to predict the acute health effects on humans of a product than the animal acute toxicity test."

- **S. 1477 To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.**

Introduced December 13, 1995, by Nancy Kassebaum (R-Kan.) and referred to the Committee on Labor and Human Resources. The act was ordered to be reported to the Senate with an amendment in the nature of a substitute on March 28, 1996. This act may be cited as the "Food and Drug Administration Performance and Accountability Act of 1995."

"Section 903(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(a)) is amended by adding the following: The mission of the [Food and Drug] Administration is to promote and protect the health of the American people by: (1) facilitating the rapid and efficient development and availability of products subject to its regulation; (2) protecting the public from unsafe or ineffective products subject to its regulation; and (3) enforcing the applicable statutes and regulations in a timely, fair, consistent, and decisive manner."

Other sections grant the Commissioner of the Food and Drug Administration authority to: establish and maintain an information system to track the status and progress of each application; establish procedures for use of policy statements; and update the procedures and conditions under which devices intended for human use may, upon application, be granted an exemption from certain requirements.

- **H. R. 2508 To amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.**

Introduced October 19, 1995, by Wayne Allard (R-Col.) and referred to the House Committee on Commerce. Referred to the Subcommittee on Health and Environment, on November 6, 1995. This act may be cited as the "Animal Drug Availability Act of 1995."

"Congress finds that: (1) the new animal drug approval process has been proceeding too slowly, with the result that necessary and useful drug therapies are being kept from the marketplace; (2) the lack of drug approvals for new animal drugs places the health and well-being of animals at risk; (3) the expense and delays caused by effectiveness testing for new animal drugs have begun to outweigh the benefits of such testing; (4) the over reliance on field investigations to establish the effectiveness of new animal drugs is a primary reason the new animal drug approval process has become so burdensome; (5) there are not sufficient approved animal drugs available to treat every specific disease or condition found in each species of animal; (6) it would benefit the public health and safety to have many additional animal drugs reviewed and approved by the Food and Drug Administration; (7) economic and regulatory incentives are necessary to encourage manufacturers of animal drugs to convert unlabeled uses of the drugs to approved, labeled uses; and (8) it is important that the Center for Veterinary Medicine of the Food and Drug Administration promptly implement the recently developed mission, vision, and guiding principles of the Center so that the Food and Drug Administration is a global leader as a public health organization that enables the marketing of safe and effective products." Related bill S. 773.

- **S. 1283 To authorize the Secretary of Agriculture to regulate the commercial transportation of horses for slaughter, and for other purposes.**

Introduced September 28, 1995, by Mitch McConnell (R-Ky.) and referred to the Committee on Agriculture, Nutrition, and Forestry. This act may be cited as the "Safe Commercial Transportation of Horses Act of 1995."

Congress finds that, to ensure that horses sold for slaughter are provided humane treatment and care, it is essential to regulate the transportation, care, handling, and treatment of horses by any person engaged in the commercial transportation of horses for slaughter.

"Minimum standards for the humane commercial transportation of horses for slaughter shall require, at a minimum, that: (1) no horse for slaughter shall be transported for more than 24 hours without being unloaded from the vehicle and allowed to rest for at least 8 consecutive hours and given access to adequate quantities of wholesome food and potable water; (2) a vehicle shall provide adequate headroom for a horse for slaughter (3) the interior of a vehicle shall be free of protrusions, sharp edges, and harmful objects, have ramps and floors that are adequately covered with a nonskid nonmetallic surface, and be maintained in a sanitary condition; (4) a vehicle shall provide adequate ventilation and shelter from extremes of weather and temperature, be of appropriate size, height, and interior design for the number of equine being carried to prevent overcrowding, and equipped with doors and ramps of sufficient size and location to provide for safe loading and unloading, including unloading during emergencies; (5) horses shall be positioned in the vehicle by size, and stallions shall be segregated from other horses ; (6) all horses for slaughter must be fit to travel as determined by an accredited large animal veterinarian." Related bill H.R. 2433.

- **S. 1459 To provide for uniform management of livestock grazing on Federal land, and for other purposes.**

Introduced December 7, 1995, by Frank Murkowski (R-Alaska) for Pete Domenici (R- New Mexico) and referred to the Committee on Energy and Natural Resources. This act passed the Senate on March 26, 1996, and was sent to the House. Referred to the House Committee on Resources and the Committee on Agriculture on March 26, 1996. The act was reported to the House with an amendment on April 25, 1996. This act may be cited as the "Public Rangelands Management Act of 1995."

Congress finds that: (1) multiple use has been and continues to be a guiding principle in the management of public lands and national forests; (2) through the cooperative and concerted efforts of the Federal rangeland livestock industry, Federal and State land management agencies, and the general public, the Federal rangelands are in the best condition they have been in during this century, and their condition continues to improve; (3) as a further consequence of those efforts, populations of wildlife are increasing and stabilizing across vast areas of the West; (4) grazing preferences must continue to be adequately safeguarded in order to promote the economic stability of the western livestock industry; (5) it is in the public interest to charge a fee for livestock grazing permits and leases on Federal land.

- **S. 1493 To amend title 18, United States Code, to prohibit certain interstate conduct relating to exotic animals.**

Introduced December 21, 1995, Frank Lautenberg (D-N.J.) and referred to the Committee on the Judiciary. This act may be cited as the "Captive Exotic Animal Protection Act of 1995."

Chapter 3 of title 18, United States Code, is amended by adding the following: "whoever knowingly transfers, transports, or possesses a confined exotic animal, for the purposes of allowing the killing or injuring of that animal for entertainment or the collection of a trophy, shall be fined under this title or imprisoned not more than one year, or both." Related bill H.R. 1202.

- **S. 1364 To reauthorize and amend the Endangered Species Act of 1973, and for other purposes.**

Introduced October 26, 1995, by Dirk Kempthorne (R-Idaho) and referred to the Committee on Environment and Public Works. This act may be cited as the "Endangered Species Conservation Act of 1995."

Congress finds that various species of fish, wildlife, and plants have become extinct as a consequence of a variety of factors, both natural and resulting from human activity. These species of fish, wildlife, and plants are necessary for maintaining biodiversity, important to future generations of Americans.

Amendments to the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) are introduced which alter wording on sections covering; endangered and threatened species determination; coordination of species conservation plans; land acquisition; interagency cooperation; international cooperation; and private property rights. Related bills: S.768, H.R. 2275, H.R. 490, S.191, H.R. 571, S.239.

- **S. 1365 To provide Federal tax incentives to owners of environmentally sensitive lands to enter into conservation easements for the protection of endangered species habitat, and for other purposes.**

Introduced October 26, 1995, by Dirk Kempthorne (R-Idaho) and referred to the Committee on Finance. This act may be cited as the "Endangered Species Habitat Protection Act of 1995."

The Senate finds the following: (1) The majority of American property owners recognize the importance of protecting the environment. (2) Current Federal tax laws discourage placement of privately held lands into endangered species conservation agreements. (3) The Federal Government should assist landowners in the goal of conserving endangered species and their habitat. (4) If the environment is to be protected and preserved, existing Federal tax laws must be modified or changed to provide tax incentives to landowners to attain such a goal.

- **H. R. 2856 To amend the Marine Mammal Protection Act of 1972 to uphold the integrity of the United States tuna labeling program, support the International Dolphin Conservation Program in the eastern tropical Pacific Ocean, and for other purposes.**

Introduced January 5, 1996, by George Miller (D-Calif.) and referred to the Committee on Resources, and in addition to the Committees on Commerce, International Relations, and Ways and Means. The Subcommittee on Fisheries, Wildlife, and Oceans held hearings on February 29, 1996. This act may be cited as the "International Dolphin Protection and Consumer Information Act of 1995."

The Congress finds the following: (1) The nations that fish for tuna in the eastern tropical Pacific Ocean have reduced dolphin mortalities associated with that fishery from hundreds of thousands annually to fewer than 5,000 annually. (2) The provisions of the Marine Mammal Protection Act of 1972 that impose a ban on imports from nations that fish for tuna in the eastern tropical Pacific Ocean have served as an incentive to reduce dolphin mortalities. (3) Consumers of the United States and Europe have made clear their preference for tuna that has not been caught through the killing, chasing, or harming of dolphins. (4) Tuna canners and processors of the United States have led the canning and processing industry in promoting a dolphin- safe tuna market. (5) The 12 signatory nations to the Declaration of Panama, including the United States, agreed under that Declaration to require that the total annual dolphin mortality in the purse seine fishery for yellowfin tuna in the eastern tropical Pacific Ocean not exceed 5,000, with a commitment and objective to progressively reduce dolphin mortality to a level approaching zero through the setting of annual limits.

The purposes of this act are: (1) to recognize that nations fishing for tuna in the eastern tropical Pacific Ocean have achieved significant reductions in dolphin mortality associated with that fishery; and (2) to eliminate the ban on imports of dolphin-safe tuna from those nations. Related bills H.R. 2823, S. 1420, H.R. 2179.

- **H.R. 2143 To amend the Packers and Stockyards Act, 1921, to make it unlawful for any stockyard owner, market agency, or dealer to transfer or market nonambulatory cattle, sheep, swine, horses, or goats, and for other purposes.**

Introduced July 31, 1995, by Gary Ackerman (D-N.Y.) and referred to the Committee on Agriculture and the Subcommittee on Livestock, Dairy, and Poultry. Executive comment requested from USDA on February 8, 1996. This act may be cited as the "Downed Animal Protection Act."

"It shall be unlawful for any stockyard owner, market agency, or dealer to buy, sell, give, receive, transfer, market, hold, or drag any nonambulatory livestock unless the nonambulatory livestock has been humanely euthanized." ■

(Note: To find out the status of these or any other bills, contact the Congressional bill status line at (202) 225-1772. This information is also available on the World Wide Web at http://thomas.loc.gov/d104/d104query.html)

Announcements...

• NIH Animal Welfare Workshop

The Office for Protection from Research Risks (OPRR), National Institutes of Health, the Institute for Laboratory Animal Resources, University of Colorado Health Sciences Center, and the University of South Colorado will be sponsoring a workshop on "The 1996 Guide for the Care and Use of Laboratory Animals: The Era of Performance-based Standards." The workshop will be held at the Adams Park Hotel in Denver, Colorado, on September 19-20, 1996. This will be the only NIH-sponsored meeting this year devoted to changes and new requirements found in the 1996 *Guide*. For more information contact Joanne Bauer, Continuing Medical Education Office, University of Colorado Health Sciences Center, 4200 East Ninth Avenue, Campus Box C295, Denver, CO 80262, phone: (800) 882-9153, fax: (303) 372-9065.

• New Publications

Animales de Experimentación--Revista Informativa de alta Tecnologia Biomedica is a Spanish language magazine, published quarterly and free of charge. The magazine is distributed internationally. The objectives of this publication are to disseminate information on scientific and technological advances related to the production and responsible care and use of experimental animals and to serve as a communication avenue among Spanish-speaking people interested in biomedical research, and laboratory animal science and medicine. To subscribe, please send your name, address, institution name, and telephone and fax number to *Animales de Experimentación*, Apdo. postal 27-281, 06761, México, D.F.

AATA Manual for the Transportation of Live Animals by Road (1996 edition) is a digest of the regulations affecting the ground transportation of animals in Europe. The manual is published by the Animal Transportation Association. The transportation of animals is controlled by European Directives that cover both the health and welfare of all animals in transit within the European Union (EU). This legislation also relates to all animals entering and leaving the EU. Third countries outside the European Community have their own legislation. This must be taken into account if animals are consigned from, to, or through them by road. This manual is a digest of the regulations in place relating to all aspects of the legislation concerning documentation, vehicle construction, specific requirements for certain species, advance arrangements, marking and labeling, and handling procedures. To order, send a check or money order for £45 or $75 to AATA, P.O. Box 251, Redhill, RH1 5FU Great Britain.

Farm Animals in Biomedical and Agricultural Research is the proceedings of a conference held by the Australia and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) in Wellington, New Zealand, on August 18-19,1995. The publication contains chapters on animal production research advancing animal welfare; contradictory standards in the laboratory, in the small animal clinic, and on the farm; agricultural research and the new ethic for animals; in vitro fertilization technologies; euthanasia; welfare issues of drug production by farm animals and drug use in farm animals; recognition of pain; and issues regarding accountability. The price for the proceedings is $A20 (including postage within Australia and New Zealand) or $A28 (including postage overseas). Copies of the proceedings may be obtained from ANZCCART, P.O. Box 19, Glen Osmond, SA 5064 Australia, phone: (08) 303 7393 or (08) 303 7325, fax: (08) 303 7113, e-mail: anzccart@waite.adelaide.edu.au

Animal Law is a journal devoted to discussing animal-related issues in law. Produced by the Northwestern School of Law at Lewis & Clark College, the journal strives to present all sides of the debate on animal rights issues and other issues relating to animals. To receive the journal or submit a manuscript, contact Animal Law, Northwestern School of Law, Lewis & Clark College, 10015 S.W. Terwilliger Blvd., Portland, OR 97219, phone: (503) 768-6798.

Methods in Cell Science is a new international, peer-reviewed journal that claims to be the only methods journal in cell science. The research relevant to this journal is conducted using in vitro systems. The journal particularly welcomes contributions that come under the category of "Alternatives to Whole Animal Studies" and would be interested in devoting an entire issue to this topic. For additional information, contact Dr. Warren I. Schaeffer, University of Vermont, Department of Microbiology and Molecular Genetics, 117 Stafford Building, Burlington, VT 05405, phone: (802) 656-2290, fax: (802) 656-8749, e-mail: wschaeff@moose.uvm.edu

Primate Care Handbook is produced by the Simian Society of America to educate those who either have or plan to have nonhuman primates in their care. Although not intended as a technical manual of primate husbandry, it contains basic information about the natural history, behavior, and care of commonly kept species. Sections also include housing, psychological well-being and environmental enrichment, socialization and reproduction, nutrition, health, and human socialization and monkey training. It is not intended to encourage the use of primates as household pets. Ordering information for *Primate Care Handbook* is available from Erin Crowley Dittmar, Information Coordinator, SSA, 6616 North Desert View Dr., Tucson, AZ 85743.

Animal Welfare: A Cool Eye Towards Eden by Professor John Webster is the result of the first Universities Federation for Animal Welfare (UFAW) Hume Fellowship. The book aims to offer constructive solutions to animal welfare problems. It is available from UFAW, 8 Hamilton Close, South Mimms, Potters Bar, Herts EN6 3QD, UK, phone: 01707 658202, fax: 01707 649279.

• New SCAW Publications and Conferences

The Scientists Center for Animal Welfare (SCAW) has several new publications and upcoming meetings. For further information about any of the items listed, contact SCAW, Golden Triangle Building One, 7833 Walker Dr., Suite 340, Greenbelt, MD 20770, phone: (301) 345-3500, fax: (301) 345-3503.

Current Issues and New Frontiers in Animal Research is the proceedings from a conference held by SCAW and the

University of Texas Health Science Center at San Antonio in December 1994. The chapter on Institutional Animal Care and Use Committee (IACUC) issues covers death as an endpoint, codes of ethics, and unaffiliated members. There is a chapter on biocontainment, biosafety, and biohazards. The final chapter "New Frontiers" covers animal models and ethical issues of xenotransplantation. The cost of the publication is $35.

Research Animal Anesthesia, Analgesia, and Surgery is the proceedings from a conference held by SCAW in Atlanta, Georgia. Topics cover surgical training and personnel qualifications, program requirements, and guidelines; recognizing pain and distress in research animals; and the use of anesthesia and analgesia during and after surgery. The cost of the publication is $55, or $35 per copy if three or more copies are ordered.

Human/Research Animal Relationship is a compilation of three workshops SCAW sponsored in 1992-1994. Chapters describe the history of the human/animal relationship, species affects, researcher and animal care staff perspectives, personnel considerations, and the influence of experimental factors on the relationship. The cost of the publication is $35.

In conjunction with the Academy of Surgical Research conference on September 5-6, 1996, in Chicago, Illinois, SCAW will sponsor a conference on "Genetic Engineering and Animal Welfare: Preparing for the Twenty First Century." Topics will include IACUC review of genetic engineering protocols, ethical issues, assessment of animal safety, transgenics and the media, agricultural animals and genetic engineering, and scientists' concerns.

SCAW, the University of Texas Health Science Center at San Antonio, and the Office for Protection from Research Risks, National Institutes of Health will co-sponsor a conference on "National IACUC Affairs" on December 5-6, 1996, in San Antonio, Texas. Topics will include animal care program structure and support, relationships with outside agencies, structure and conduct of IACUC meetings, the role of the non-affiliated IACUC member, and program evaluation.

• Robert Van Buskirk Wins Russell and Burch Award

The Humane Society of the United States (HSUS) presented the fifth annual Russell and Burch Award to Robert Van Buskirk, a biologist at the State University of New York at Binghamton, who has developed procedures that decrease the use of animals in safety testing. The award recognizes a scientist who has made outstanding contributions toward the advancement of alternatives to the use of animals in research, testing, or education.

Van Buskirk won the award for developing a synthetic human skin that can substitute for the use of animals in skin testing. The synthetic skin is currently being marketed by Mat-Tek Corporation and being used by over half of the major U.S. pharmaceutical/cosmetic companies as an animal alternative. He has also developed a sophisticated in vitro procedure and analytical device that can assess chemical damage to cells without using animals.

• Research Library for Animal Advocacy Established

The John Marshall Law School in Chicago, Illinois, has joined with the National Anti-Vivisection Society (NAVS) to establish the Research Library for Animal Advocacy. As part of the Law School's Center for Advocacy, the library will contain printed resources to assist in the research and development of arguments pertaining to animal protection issues. NAVS hopes the library will be the start of a network of animal resource centers around the country. The library is looking for donations of suitable books. For further information, contact Marcia Goodman, Publications Editor, National Anti-Vivisection Society, 53 West Jackson Blvd., Chicago, IL 60604-3795, phone: (312) 427-6065, fax: (312) 427-6542, e-mail: navs@navs.org

• NCAB/AALAS

The National Capital Area Branch of the American Association for Laboratory Animal Science (NCAB/AALAS) annual seminar will be held at the Turf Valley Hotel and Country Club in Ellicott City, Maryland, on September 18-19, 1996. The seminar is entitled "Laboratory Animal Science and Chemistry--Reactions and Solutions." For further information, contact Bruce Kennedy at phone: (301) 402-6731, fax: (301) 480-0098 or Charlie Kammer at phone: (410) 529-4762, fax: (410) 529-2007.

• World Animal Care Foundation

The World Animal Care Foundation (WACF) was formed in 1991 to support and promote responsible animal care and use. It seeks to educate animal owners and the general public about proper stewardship and responsibility regarding animal care. It supports and promotes the responsible use of animals in medical research, recreation, sport, agriculture, and companionship. WACF has produced education materials and supports a pet loss hot line, an animals-in-prison program, an assistance program for pet owners, and an elderly care visitation program. It made human-animal bond awards available to 26 veterinary colleges in 1995. For more information, contact World Animal Care Foundation, 17200 SE 58th Ave., Summerfield, FL 34491, phone: (904) 245-2615, fax: (904) 245-1248.

• MMWR On-Line

The *Morbidity and Mortality Weekly Report* (*MMWR*) is produced by the Centers for Disease Control and Prevention and reports on timely public health topics such as emerging infectious diseases, immunizations, and environmental health. It is now available free of charge to the general public through the Internet and e-mail subscriptions. The table of contents of each issue is sent electronically to subscribers the day that it is published. Also sent are instructions on how to download the complete file. Users must have Internet access via e-mail, software that retrieves documents by file transfer protocol (ftp), or software that can access the World Wide Web. Past copies of *MMWR* (since January 15, 1993) are also available online. To view the *MMWR*, Adobe Acrobat Reader is required. Copies may be freely downloaded from this site.

To subscribe, send an e-mail message to: **lists@list.cdc.gov** The body content of the message should read: **subscribe mmwr-toc**. You will be added to the mailing list and receive the weekly table of contents and instructions about additional e-mail commands.

To receive *MMWR* via FTP, contact the file server and enter the user name **anonymous**. Select the subdirectory **/pub/publications** then the subdirectory **mmwr**. Select subdirectory **wk** for *MMWR* (weekly), subdirectory **ss** for *CDC Surveillance Summaries*, or subdirectory **rr** for *MMWR Recommendations and Reports*. Then view the lists and download whatever binary files you choose.

To access *MMWR* publications on the World Wide Web, connect to **http://www.cdc.gov/** Go to **Publications, Products, and Subscription Services** to find the *MMWR*. Download the binary file by selecting the *MMWR* title of your choice.

• World Wide Web Sites

FDA Approved Animal Drug Database

The Food and Drug Administration has put its list of approved animal drugs on the World Wide Web. The database is keyword and boolean searchable. It can be accessed at **http://scholar.lib.vt.edu/ejournals/vetfda.html**

Americans for Medical Progress

Americans for Medical Progress has two new websites. Background notes, articles, and other resources on the medical research vs. animal rights debate can be found at **http://www.ampef.org**

A page that is dedicated to late-breaking news of interest to the research community is at **http://www.ampef.org/news**

For more information or to make comments and suggestions about the sites, contact Americans for Medical Progress at phone: (703) 836-9595, fax: (703) 836-9594, e-mail: AMPEF@aol.com

Zoonoses Websites

University of California Santa Barbara (UCSB) has an animal care website that features training information for researchers working with specific species, tips on searching for alternatives, guidelines for reporting concerns, UC policy statements on animal use, overviews of laws relating to animal care and use, and zoonotic diseases. The zoonotic disease page allows searching for disease information by animal reservoir or disease. The URL is **http://omni.ucsb.edu/pro/acc-home.html**

A new website that addresses reptile-associated Salmonellosis can be found at **http://www.xmission.com/~gastown/herpmed/salm.htm**

Topics addressed are routes of transmission, prevention, case histories, and bibliographic references. ■

Correction

In the last issue of *Animal Welfare Information Center Newsletter* (Winter 1995/1996, Vol. 6, No. 2-4), the bitnet address for the American Psychological Association's Research Funding Bulletin (APASD-L) was incorrect. The correct addresses are Bitnet: listserv@vtvm1 or Internet: listserv@vtvm1.cc.vt.edu

Working for Animals used in Research, Drugs, and Surgery

WARDS

Recognizing the importance of medical experimentation and its potential for enhancing the lives of humans as well as animals, a group of concerned citizens founded Working for Animals used in Research, Drugs and Surgery (WARDS) in 1953.

The initial purpose of the organization was to unite the research community with the general public in hopes of reaching a mutually beneficial common ground that would ensure the most ethical and humane care possible for animals without hindering scientific advancement. Building on its valuable contributions toward the design and implementation of the Laboratory Animal Welfare Act in 1966, WARDS continues today to work toward its original objectives.

Over the past 42 years, the organization has developed excellent working relationships with scientists, veterinarians and educators. Through such efforts, WARDS has succeeded in motivating discussion that has led to many major advancements for the care of animals. Among its ongoing programs, WARDS has funded studies and reports conducted by the Tufts University Center for Animals and Public Policy and cosponsored conferences with the Scientists Center for Animal Welfare to encourage progressive attitudes toward animal care. The organization also funds an annual scholarship program for selected junior and senior veterinary students at the Virginia-Maryland Regional College of Veterinary Medicine.

Through its two quarterly publications, WARDS informs both the general public and the scientific community of the latest issues affecting animal welfare. *Our Animal WARDS* is primarily designed for the general public and contains articles of interest to people concerned with the care of all animals. *Science and Animal Care* is distributed to the scientific community and focuses on the technical aspects of animal welfare. Written manuscripts for either publication are welcomed and may be submitted for consideration.

WARDS serves as a voice for those in the general public who believe that rational discussion and debate provide the best means to promote animal welfare. To maintain its integrity, WARDS has never accepted financial support from pharmaceutical companies or the biomedical research community.

For more information, please contact Christopher Byrnes, WARDS Director of Public Relations, 8150 Leesburg Pike, Suite 512, Vienna, Virginia 22182-1655, Tel: (703) 442-4511 or (800) 876-5572, Fax: (703) 442-4729. ■

Grants...

• NCRR Comparative Medicine Research and Resource Grant Support

The National Center for Research Resources (NCRR) is accepting applications for several research grants. Animal (mammalian and nonmammalian) Model and Animal and Biological Material Resource Grants (P40) are used to provide support for special colonies of laboratory animals as well as for other resources such as culture cells and genetic stocks that serve the biomedical community at large.

Grants for Regional Primate Research Centers (P51) support distinct organizations affiliated with academic institutions to provide facilities, personnel, equipment, breeding colonies of nonhuman primates, and other support needed by investigators to conduct research programs.

Investigators-initiated research projects (R01 and R29) provide for the exploration and development of new models (animal, computer, mathematical, etc.) or for research to expand the usefulness of established model systems.

For further information contact: Dr. Leo A. Whitehair, Director, Comparative Medicine, National Center for Research Resources, One Rockledge Centre, Suite 6030, 6705 Rockledge Dr., MSC 7965, Bethesda, MD 20892-7965; phone: (301) 435-0744; e-mail: LeoW@EP.NCR.NIH.GOV

• Doerenkamp-Zbinden Foundation

The Foundation has announced the availability of two awards for 1996-1997 for research on alternatives to the use of animals. Each award will total from 25,000 to 50,000 SF. One award will be given for research demonstrating in vitro methods or ethically acceptable experiments in humans that can replace the use of animals in experiments. The second award will be made for techniques, instruments, or drugs that have produced a clear reduction in suffering in animals used in experiments.

Nominations will be judged by a board consisting of research scientists and lay people. Submissions will be assessed for scientific quality and relevance to animal welfare. Nominations for these awards should be made to: Prof. Dr. med. Dr. h.c. K. Brune, Institute of Experimental and Clinical Pharmacology and Toxicology, Universtatsstr. 22, D-91054 Erlangen, Germany.

The closing date for nominations is October 1, 1996.

• Hastings Center Programs

Student Intern Program

The Center has a research program in several fields including biomedical and environmental ethics and studies ethical and philosophical issues relating to organ transplantation, law, science, animal welfare, etc. The intern's research must be in an area of bioethical issues, and prior training in the field is required.

International Biomedical Ethics Research Program

This program is designed for advanced scholars and medical professionals who have made or will make significant contributions to bioethics in their countries.

Journalist-in-Residence Program

Journalists covering medical and scientific issues are provided the opportunity to perform research on topics of interest to their readers. The internship typically lasts for not longer than 1 month.

Visiting Scholar Program

Professional in the academic, biomedical, or legal fields performs independent research on ethical issues in medicine, biosciences, and related fields. The typical stay at the Center is 2 weeks to 1 month.

For more information about the center's programs, contact Strachan Donnelley, Director of Education, Hastings Center, 255 Elm Rd., Briarcliff Manor, NY 10510, phone: (914) 762-8500, fax: (914) 762-2124.

• International Program for Animal Alternatives

The Procter and Gamble Company supports research for the development of new technologies that will replace or reduce the numbers of animals or reduce the distress imposed on animals currently used in testing the safety and efficacy of drugs and consumer products. Three grants will be awarded. The maximum award will be $50,000 annually for up to 3 years. The deadline for submission of proposals is September 1, 1996. For additional information, please contact the Program Administrator, International Program for Animal Alternatives, Procter and Gamble Company, Miami Valley Laboratories, P.O. Box 538707, Cincinnati, OH 45253-8707 USA, fax: (513) 627-1153.

• Ethical Research Grants and Fellowships--Alternatives

The International Foundation for Ethical Research has grants and fellowships available for scientists performing research seeking alternatives to the use of live animals in research, testing, and teaching. Areas of interest include: tissue culture, bacterial cultures, protozoan studies, mathematical and computer models, etc. Individuals or organizations from around the world are encouraged to apply. The preproposal deadline is August 1, 1996. For more information, contact the International Foundation for Ethical Research, 53 W. Jackson Blvd., Suite 1552, Chicago, IL 60604 USA, phone: (312) 427-6025.

• Foundation Research 3R - Stiftung Forschung 3R - Fondation Recherches 3R

Foundation Research 3R has announced a call for proposals for the 1997 grant year. Applications will be evaluated for relevance to the 3R's--reduce, refine, replace--practical application to the 3R's, potential regulatory impact, and scientific issues. The deadline for submission is October 1, 1996. For more information, contact R. Greber at phone: 031-323 83 83, fax: 031-323 80 02, e-mail: greber@ivi.ch or write to Stiftung Forschung 3R, Secretariate, P.O. Box 149, CH-3110 Münsingen, Switzerland. ■

Upcoming Meetings

American Institute for Biological Science, August 4-8, 1996. Seattle, Washington, USA. Contact phone: (202)628-1500.

American Psychological Association, August 9-13, 1996. Toronto, Ontario, Canada. Contact phone: (202) 336-5500.

Fourth International Conference on Simulation of Adaptive Behavior (SAB96): From Animals to Animats, September 9-13, 1996. Cape Cod, Massachusetts, USA. Contact e-mail: sab96@cs.brandeis.edu or WWW: http://www.cs.brandeis.edu/conferences/sab96

Society of Research Administrators Annual Meeting, October 6-9, 1996. Toronto, Ontario, Canada. Contact phone: (202) 857-1141.

The 10th International Mouse Genome Conference, October 8-11, 1996. Paris, France. Contact phone: 33 1 45 68 85 55, fax: 33 1 45 68 86 39 - Jean-Louis Guenet, e-mail: guenet@pasteur.fr In the United States, contact phone: (716) 845-4390, fax: (716) 845-8169, e-mail: dmiller@mcbio.med.buffalo.edu

National Association of Biology Teachers (NABT) Annual Meeting, October 16-19, 1996. Charlotte, North Carolina, USA. Contact phone: (703) 471-1134.

National Science Teachers Association, Western Region, October 17-19, 1996. Phoenix, Arizona, USA. Contact phone: (703) 312-9363, e-mail: conventions@nsta.org

2nd World Congress on Alternatives and Animal Use in the Life Sciences, October 20-24, 1996. Utrecht , The Netherlands. Contact phone: +31.30.53.5044/2728, fax: +31.30.53.3667 or e-mail: l.donkers@pobox.ruu.nl

National Science Teachers Association, Southern Region, October 31-November 2, 1996. Atlanta, Georgia, USA. Contact phone: (703) 312-9363, e-mail: conventions@nsta.org

National AALAS Annual Meeting, November 3-7, 1996. Minneapolis, Minnesota, USA. Contact phone: (901) 754-8620.

American College of Toxicology Annual Meeting, November 10-13, 1996. Valley Forge, Pennsylvania, USA. Contact phone: (301) 571-1840, fax: (301) 571-1852.

American Heart Association Annual Meeting, November 11-14, 1996. New Orleans, Louisiana, USA. Contact phone: (214) 706-1230.

Society for Neuroscience Annual Meeting, November 16-21, 1996. Washington, D.C., USA. Contact phone: (202) 462-6688.

National Science Teachers Association, Eastern Region, and Science Teachers Association of Ontario, November 21-23, 1996. Toronto, Ontario, Canada. Contact phone: (703) 312-9363, e-mail: conventions@nsta.org

FASEB International Congress for Cell Biology, December 7-11, 1996. San Francisco, California, USA. Contact phone: (301) 530-7010.

European Congress on the Ethics of Animal Experimentation, December 16-18, 1996. Brussels, Belgium. Contact: e-mail: secretariat@ebra.org (send name and address to receive program by mail).

National Science Teachers Association Global Summit on Science and Science Education, December 27-29, 1996. San Francisco, California, USA. Contact phone: (703) 312-9363, e-mail: conventions@nsta.org ■

"Meeting the Information Requirements of the Animal Welfare Act"

The Animal Welfare Information Center (AWIC) of the U.S. Department of Agriculture, National Agricultural Library (NAL) has developed a 2-day workshop for individuals who are responsible for providing information to meet the requirements of the Animal Welfare Act. The workshop will be held at NAL in Beltsville, Maryland.

The act requires that investigators provide Institutional Animal Care and Use Committees (IACUC) with documentation demonstrating that a thorough literature search was conducted regarding alternatives. An alternative is any procedure that results in the reduction in the numbers of animals used, refinement of techniques, or replacement of animals.

The objectives of the workshop are to provide:

- an overview of the Animal Welfare Act and the information requirements of the act.
- a review of the alternatives concept.
- a comprehensive introduction to NAL, AWIC, and other organizations.
- instruction on the use of existing information databases/networks.
- online database searching experience.

This workshop is targeted for principal investigators, members of IACUC's, information providers, administrators of animal use programs, and veterinarians. All participants will receive a resource manual.

The workshop will be held on November 14-15, 1996. The workshop will be limited to 20 people. There is presently no fee for the workshop.

For more information, contact AWIC at Tel: (301) 504-6212, Fax: (301) 504-7125, or e-mail: awic@nal.usda.gov, or write to:

Animal Welfare Information Center, U.S. Department of Agriculture, National Agricultural Library, 10301 Baltimore Avenue, Beltsville, MD 20705-2351

THE ANIMAL WELFARE ACT
Historical Perspectives–Future Directions

USDA to Sponsor Symposium Celebrating the 30th Anniversary of the Animal Welfare Act and the 10th Anniversary of the Animal Welfare Information Center on September 12-13, 1996

The Regulatory Enforcement and Animal Care unit of the Animal and Plant Health Inspection Service (APHIS) and the Animal Welfare Information Center (AWIC) of the National Agricultural Library, U.S. Department of Agriculture, will sponsor a 1-day symposium on September 12, 1996, to mark the 30th anniversary of the Animal Welfare Act. It will be held at the APHIS building in Riverdale, Maryland. The symposium will take a retrospective look at the development and impact of animal welfare regulations in the United States since the passage of the Laboratory Animal Welfare Act in 1966. Leaders from government, industry, and humane groups will offer their unique viewpoints on the impact of the regulations and offer insight as to the future of animal welfare and regulatory oversight.

To mark its 10th anniversary, the Animal Welfare Information Center will hold an open house on September 13, 1996, at the AWIC offices at the National Agricultural Library in Beltsville, Maryland. The AWIC staff will be presenting a 3-hour seminar on meeting the information requirements of the Animal Welfare Act. Tours will also be available of the National Agricultural Library, the Beltsville Agricultural Research Center, and the National Wildlife Visitors Center at the Patuxent Environmental Science Center.

Researchers, regulatory personnel, animal care and use committee members, veterinarians, administrators, and others concerned about animal welfare regulatory activities are encouraged to attend. For additional information, contact:

Tim Allen, U.S. Department of Agriculture, Animal Welfare Information Center, 10301 Baltimore Avenue, Beltsville, MD 20705-2351, Phone: (301) 504-6212, Fax: (301) 504-7125, e-mail: tallen@nal.usda.gov

Joy DeArce, U.S. Department of Agriculture, Regulatory Enforcement and Animal Care, 4700 River Road, Suite 6D14, Riverdale, MD 20737-1234, Phone: (301) 734-7316, Fax: (301) 734-4978.

United States Department of Agriculture
Agricultural Research Service
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Michael Kreger, Assistant Editor
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